IN THE SUPREME COURT

OF THE STATE OF NEVADA

Supreme Court Case No.: 81024

Dist. Court Case No.: A-18-778471-C
Consolidated with: A-18-781820-C
A-18-782023-C

TEVA PARENTERAL MEDICINES, INC., fka SICOR, INC.; BAXTER HEALTHCARE CORPORATION; and MCKESSON MEDICAL-SURGICAL INC.,

Petitioners,

v.

THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, IN AND FOR THE COUNTY OF CLARK; THE HONORABLE TREVOR ATKINS, DISTRICT JUDGE, DEPT. 8; THE HONORABLE NANCY ALLF, DEPT. 27; and THE HONORABLE JIM CROCKETT, DISTRICT JUDGE, DEPT. 24,

Respondents,

And concerning:

YVETTE ADAMS; MARGARET ADYMY; THELMA ANDERSON; JOHN ANDREWS; MARIA ARTIGA; LUPITA AVILA-MEDEL; HENRY AYOUB; JOYCE BAKKEDAHL; DONALD BECKER; JAMES BEDINO; EDWARD BENAVENTE; MARGARITA BENAVENTE; SUSAN BIEGLER; KENNETH BURT; MARGARET CALAVAN; MARCELINA CASTANEDA; VICKIE COLE-CAMPBELL; SHERRILL COLEMAN; NANCY COOK; JAMES DUARTE;

PETITIONER'S APPENDIX

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and

SOSSY ABADJIAN; GLORIA ACKERMAN; VIRGINIA ADARVE; FRANCIS ADLER; CARMEN AGUILAR; RENE NARCISO; RHEA ALDER; GEORGE ; ALLSHOUSE SOCORRO ALLSHOUSE; LINDA ALPY; JOYCE ALVAREZ; REBECCA L. ANDERSON ANDREI; EMANUEL; TERRIE ANTLES; KELLIE APPLETON-HULTZ; ANTHONY ARCHULETA; ESTEBAN ARELLANOS; RICKIE ARIAS; MARK ARKENBURG; ROGER ARRIOLA; MARIA ARTIGA; ROBIN ASBERRY; WINIFRED BABCOCK; ROBERT BACH; SUSAN F. BACHAND; ELAINE BAGLEY-TENNER; MELISSA BAL; BRYAN BALDRIDGE; RONALD BARKER; RONALD BARNCORD; PEGGY JO BARNHART; DONALD BARTLETT; SHERYLE BARTLETT; JOSEPH BAUDOIN; BARBARA BAXTER; VENUS BEAMON; BARBARA ROBIN BEATTY; RODNEY BEHLINGS; CRISTINA BEJARAN; TOMAS BENEDETTI; VERNA BENFORD; RICHARD BENKERT; MARSHALL BERGERON; DONNA BERGERON; SYLVIA BIVONA; ROBERT BLAIR; HARRY BLAKELEY; DAWN BLANCHARD; BONNIE BLOSS; DARRELL BOLAR; ROY BOLDEN; VICTOR BONILLA; GRACIELA BORRAYES; BILLY BOWEN; SHIRLEY BOWERS; SHIRLEY BRADLEY; CARLA BRAUER; CAROLYN BROWN; JACK BROWN; LESLIE BROWN; MICHAEL BROWN; ROBERTA BROWN; AMELIA B.

BRUNS; CARL L. BURCHARD; TRACI BURKS; ELIZABETH BURTON; ANGELITE BUSTAMANTE- RAMIREZ; ANASTASIO BUSTAMANTE; DOROTHY ANN BUTLER; LEE CALCATERRA; EVELYN CAMPBELL; MARIA CAMPOS; BOONYUEN CANACARIS; MELISSA CAPANDA; MARTIN CAPERELL; PEDRO CARDONA; SUSIE CARNEY; TERESA CARR; BERNARDINO CARRASCO; TRUMAN CARTER; XANDRA CASTO; SPENCE CAUDLE; MARGARET CAUSEY; XAVIER CEBALLOS; ROBERT CEDENO; DINORA CENTENO; ROY CHASE; CARIDAD CHEA; ELSA CHEVEZ; LUCILLE CHILDS; ALICIA CLARK; CAROL CLARK; PATRICIA CLARK; RICHARD COIRO; PERCELL COLLINS, JR.; ERNEST CONNER; SUSAN COREY; PATRICIA CORREA; PAUL A. COULOMBE; AMBER CRAWFORD; RONALD CROCKER; HOWARD CROSS; ROSSLYN CROSSLEY; WILLIAM R. DANIELS.; EVELYN DAVIS; MARY JEAN DAVIS; VIRGINIA A. DAVIS; JESSIE L. DAWSON; EMELYN DELACRUZ; SILVIA DERAS; SHERIDA DEVINE; CLAIRE DIAMOND; JOSE DIAZ-PEREZ; OTIS L. DIXON; EMILIO DOLPIES; PAMELA DOMINGUEZ; EUQENA DOMKOSKI; JOSEPH DONATO; HUGO DONIS; PATRICIA L. DONLEY; LJUBICA DRAGANIC; DELORIS K. DUCK; KATHLEEN J. DUHS; LILLIAN DUNCAN; HAROLD DUSYK; ALLYSON R. DYER, JR.; LOIS EASLEY; DEISY ECHEVERRIA; ROLAND E. ELAURIA; DARIO E. ESCALA; ENGARCIA B. ESCALA; KATHY A. ESCALERA; MARIA ESCOBEDO; TERESA I. ESPINOSA; LEON EVANS;

MARY FAULKNER; ABRAHAM FEINGOLD; MURIEL FEINGOLD; OSCAR FENNELL; MARIETTA FERGUSON; WILLIE FERGUSON; DANIEL FERRANTE; CAROLYN FICKLIN; JOE FILBECK; ETHEL FINEBERG; MADELINE C. FINN; ALBERT L. FITCH; ADRIAN FLORES; MARIA FLORES;; RAUNA FOREMASTER; JOSEPH E. FOSTER; PHYLLIS G. FOSTER; CYNTHIA D. FRAZIER; VICTORIA FREEMAN; LAWRENCE FRIEL; BONITA M. FRIESEN; NESS FRILLARTE; NANCY C. FRISBY; JODI GAINES; ESPERANZA GALLEGOS; NEOHMI GALLEGOS; BRENDA GARCIA; MARTHA GARCIA; SANDRA GARDNER; MICHAEL GARVEY; E THERESA GEORG; TINA GIANNOPOULOS; ARIS GIANNOPOULOS; WANDA GILBERT; JEAN GOLDEN; GOLOB LUCIANO; PASTOR GONZALES; JESUS GONZALEZ-TORRES; JEFF GOTLIEB; ALLEN GOUDY; BILL GRATTAN; ARNOLD GRAY; BONNIE GRAY; TANIA GREEN; ROY GREGORICH; WILLIE GRIFFIN; VERNA GRIMES; CANDELARIO GUEVARA; NICHOLAS GULLI; JULIA GUTIERREZ; DENISE F. HACHEZ; SUE HADJES; FRANK J. HALL; TINA HALL; CHARDAI C. HAMBLIN; ROBERT HAMILTON, JR.; JOANN HARPER; DORIS HARRIS; GLORICE HARRISON; SHARA HARRISON; RONALD K. HARTLEY; ESTHER A. HAYASHI; SAMUEL HAYES; CANDIDO HERNANDEZ; MARIA HERNANDEZ; THOMAS HERROLD; LUZ HERRON; SUSAN M. HILL; ISHEKA HINER; ARLENE HOARD; BETH HOBBS; MICHELLE HOLLIS; JAQUELINE A. HOLMES; JAMES HORVATH; ANA

HOSTLER; AUGUSTAVE HOULE; CARL II; HOWARD HOVIETZ; RUTH HOWARD; MICHELE HOWFORD; EDWARD L. HUEBNER; LOVETTE M. HUGHES; VIRIGINIA M. HUNTER; PATRICIA HURTADO-MIGUEL; ANGELA HYYPPA; JOSEPH INFUSO; FRANK INTERDONATI; BRIAN IREY; CECIL JACKSON; ROLANDO JARAMILLO; RICHARD JILES; LETHA JILES; CLIFTON JOHNSON; DORIS JOHNSON; JOHNNY JOHNSON; JOYCE JOHNSON; ARNOLD JONES; ANN KABADAIAN; ANTHONY K. KALETA; ARUN KAPOOR; LINDA J. KEELER; MICHAEL F. KELLY; DARRELL KIDD; CONNIE KIM; SOO-OK KIM; TAESOOK KIM; SONDRA I. KIMBERS; ELIZABETH I. KINDLER; IRIS L KING; JOANNA KOENIG; MICHAEL J. KRACHENFELS; CORINNE M. KRAMER; DAVID KROITOR; OLGA KUNIK; KAREN A. KUNZIG; ANEITA LAFOUNTAIN; BARBARA LAKE; BERTHA LAUREL; ANGES G. LAURON; MARIE LAWSON; PHYLLIS LEBLANC; ARLENE LETANG; JAMES A. LEWIS; JOAN LIEBSCHUTZ; MINERVA L. LIM; EDWARD LINDSEY; WILLIAM LITTLE; DOROTHY LIVINGSTON-STEEL; FELISA LOPEZ; IRAIDA LOPEZ; NOE LOPEZ; FLORENCE LUCAS; DARLENE LUTHER; FRANK L LYLES; DEBORAH MADRID; MARWA MAIWAND**; DOROTHY J. MAJOR; MARIO MALDONADO; IDA MALWITZ; AUDREY MANUEL; GABRIEL MARES; CAROL A. MARQUEZ.; HUGO MARTINEZ; JORGE B. MARTINEZ; JOSE MARTINEZ; MARY LOUISE MASCARI; LUCY MASTRIAN; LEROY MAYS; LISA MAYS; VIRGINIA A. MCCALL ; STELLA

MCCRAY; LAURENCE MCDANIEL; JOHN MCDAVID, JR.; DOLORES MCDONNELL; DENISE ANNE MCGEE; MAE MCKINNEY; JANET MCKNIGHT; FRED MCMILLEN, III; MYRON MEACHAM; AIDA A. MEKHJIAN; CHELSEY L. MELLOR; JIGGERSON MENDOZA; SUSAN MERRELL-CLAPP; JAMES MIDDAUGH; SYLVIA MILBURN; CORINNE MILLER; JANICE MITCHEL; MIKHAIL MIZHIRITSKY; KIRK MOLITOR; MARY MOORE; JOSE MORA; YOLANDA MORALES; ELIZABETH CASTRO MORALES;YOLANDA MORCIGLIO; BIVETTA MORENO; DAVID MORGAN; DENISE M. MORGAN; DOUGLAS MORGAN; SONIA MORGAN; ANDREW MORICI; BARRY MORRIS; JAMES MORRIS; JUANITA E. MORRIS; MICHELE MORSE; DAN R. MORTENSEN; MIGDALIA MOSQUEDA; ANDREA MOTOLA; ANNIE MUNA; LUCILA MUNGUIA; WILLIE MURRAY; JOSEPH NAGY; BONNIE NAKONECZNY; ERLINDA NATINGA; LEEANNE NELSON; LANITA NEWELL ; ROSEMARIE NORLIN; MARSHALL NYDEN; WADE OBERSHAW; JOSEPH O’CONNELL; DIGNA OLIVA; JOHN O'MARA; L NORMA J. O'NEA; LINDA ORCULLO; PAULA OROZCO-GALAN; ANGELA PACHECO; DENIS PANKHURST; MATT PARK; KATHY PARKINSON; JESUS PAZOS; TERESA PECCORINI; PHYLLIS PEDRO; JOSE O. PENA; PATRICIA PEOPLES; DELMY C. PERDOMO; DORA PEREZ; LOUISE PEREZ; LUIS PEREZ; MARIA PEREZ; MERCEDES PEREZ; AGUSTIN PEREZ-ROQUE; ANDRE PERRET; JANET P. PERRY; ALAN K.

PETERSON; LOWELL PHILIP; MICHELLE PHILIP; DONALD PINSKER; JASON B. PITMAN; WAYNE PITTMAN; RON POLINSKI; MOHAMMED POURTEYMAUR; DONNA POWERS; EVA POWERS; JENNIFER POWERS; JOSE PRIETO; LUISA PRIETO; FRANCISCO QUINTERO; ANTHONY RAY QUIROZ; MARIBEL RABADAN; ADRIANA RAMIREZ; JOHN RAMIREZ; RAUL RAMIREZ; ROBERT RAPOSA; CELIA REYES DE MEDINA; GABRIEL REYES; MIGUEL REYES; BARBARA ROBERTS; CONSTANCE ROBINSON; LLOYD H. ROBINSON; CONNIE ROBY; ANTOINETTE ROCHESTER; VICKI RODGERS; TREVA RODGERS; MARIA RODRIGUEZ; NENITA RODRIGUEZ; RICARDO RODRIGUEZ; YOLANDA RODRIGUEZ; JOSE RODRIGUEZ-RAMIREZ; FREEMAN ROGERS; CAROLE ROGGENSEE; SONIA ROJAS; JOSEPH ROMANO; JEAN ROSE; ROSETTA RUSSELL; DEMETRY SADDLER; JANISANN SALAS; MARIA SALCEDO; KERRI SANDERS; LOVIE SANDERS; SHERRILYN SAUNDERS; ISA SCHILLING; RAY SEAY; SANDRA SENNESS; ANTHONY SERGIO, JR.; SYLVIA SHANKLIN; DOUGLAS SHEARER; SANDRA SIMKO; JAMES SLATER; JACKLYN SLAUGHTER; JOHN SLAUGHTER; CATHERINE SMITH; WILBUR SMITH; LILA SNYDER; DOLORES SOBIESKI; WAYNE SOMMER; MARIA SOTO; JULIE SPAINHOUR; JESSICA SPANGLER; PATRICIA SPARKS; WILLIAM STANKARD; GINGER STANLEY; RODNEY STEWART; LETICIA STROHECKER; HAROLD STROMGREN;

MAFALDA SUDO; BARBARA SWAIN; NORMA TADEO; MIRKA TARNOWISKI; RYSZARD TARNOWSKI; ROXANNE E. TASH; JILL TAYLOR; JEANNE THIBEAULT; CATHERINE TITUS-PILATE; RAYMOND TOPPLE; DOMINGA TORIBIO; YADEL TORRES; RITA M. TOWNSLEY; ROSELYN TRAFTON; SALVATORE TROMELLO; PATRICIA A. TROPP; DOROTHY TUCKOSH; LUCY TURNER; TERRY TURNER; ROBERT TUZINSKI; WILLIAM UNRUH; JESUS VALLS; DIANNE VALONE; HILLEGONDA VANDERGAAG; HENRY VELEY; STELLA VILLEGAS; LOUIS VIRGIL; CECILIA VITAL-CEDENO; COLLEEN VOLK; CHRIST VORGIAS; WILLIAM WADLOW; BETTY WAGNER; JOHN WALTERS; JASON WALTON; JANICE WAMPOLE; BARBARA WARD; GLORIA WARD; SANDRA WARIS; LESTER WEDDINGTON; ARLENE WEISNER; KATHRYN WHEELER; FRANK E. WHITE; SERENE WHITE; SHARON WHITE; BRIDGET WILKINS; ACE K. WILLIAMS; ANTHONY WILLIAMS; AUBREY WILLIAMS; CHARLES WILLIAMS; CHERYL WILLIAMS; MARY WILLIAMS; WILLIE WILLIAMS; GARY WILSON; ROBERT WILSON; STEVEN WILT; ANGELA WINSLOW; BEVERLY WINTEROWD; BETTY WINTERS; JAMES WOLF; DEREK WORTHY

and

MAUREEN BRIDGES; MARIA LISS; MARY CATTLEDGE; FRANKLIN CORPUZ; BARBARA EDDOWES; ARTHUR EINHORN; CAROL EINHORN;

WOODROW FINNEY; JOAN FRENKEN; EMMA FUENTES; JUDITH GERENCES; ANNIE GILLESPIE; CYNTHIA GRIEM-RODRIGUEZ; DEBBIE HALL; LLOYD HALL; SHANERA HALL; VIRGINIA HALL; ANNE HAYES; HOMERO HERNANDEZ; SOPHIE HINCHLIFF; ANGEL BARAHONA; MARTA FERNANDEZ VENTURA; WILLIAM FRALEY; RICHARD FRANCIS; GEORGINA HETHERINGTON; JANICE HOFFMAN; GEORGE JOHNSON; LINDA JOHNSON; SHERON JOHNSON; STEVE JOHNSON; SEAN KEENAN; KAREN KEENEY; DIANE KIRCHER; ORVILLE KIRCHER; STEPHANIE KLINE; KIMBERLY KUNKLE; PATRICIA LEWIS-GLYNN; BETTE LONG; PETER LONGLY; DIANA LOUSIGNONT; MARIA KOLLENDER; DAVID MAGEE; FRANCISCO MANTUA; DANA MARTIN; MARIA MARTINEZ; JOHN MAUIZIO; ANGA MCCLAIN; BARRY MCGIFFIN; MARIAN MILLER; HIEP MORAGA; SONDRA MORENO; JIMMY NIX; NANCY NORMAN; GEORGIA OLSON; MARK OLSON; BEVERLY PERKINS; MARYJANE PERRY; RICKY PETERSON; BRANDILLA PROSS; DALLAS PYMM; LEEANN PINSON; SHIRLEY PYRTLE; EVONNE QUAST; RONALD QUAST; LEANNE ROBIE; ELEANOR ROWE; RONALD ROWE; DELORES RUSS; MASSIMINO RUSSELLO; GEOLENE SCHALLER; JAN MICHAEL SHULTZ; FRANCINE SIEGEL; MARLENE SIEMS; RATANAKORN SKELTON; WALLACE STEVENSON; ROBERT STEWART; RORY SUNDSTROM; CAROL SWAN; SONY SYAMALA; RICHARD TAFAYA;

JACQUELINE BEATTIE; PRENTICE BESORE; IRENE BILSKI; VIOLA BROTTLUND-WAGNER; PATRICK CHRISTOPHER; PAUL DENORIO; DAVID DONNER; TIMOTHY DYER; DEMECIO GIRON; CAROL HIEL; CAROLYN LAMYER; REBECCA LERMA; JULIE KALSNES f/k/a OLSON; FANNY POOR; FRANCO PROVINCIALI; JOELLEN SHELTON; FRANK STEIN; JANET STEIN; LOIS THOMPSON; FRANK TORRES; FRANK BEALL; PETER BILLITTERI; IRENE CAL; CINDY COOK; EVELYN EALY; KRISTEN FOSTER; PHILLIP GARCIA; JUNE JOHNSON; LARRY JOHNSON; WILLIAM KEPNER; PEGGY LEGG; JOSE LOZANO; JOSEPHINE LOZANO; DEBORAH MADISON; MICHAEL MALONE; ANN MARIE MORALES; GINA RUSSO; COLLEEN TRANQUILL; LORAINE TURRELL; GRAHAM TYE; SCOTT VANDERMOLIN; LOUISE VERDEL; J. HOLLAND WALLIS; ANGELA HAMLER f/k/a WASHINGTON; SHARON WILKINS; MARK WILLIAMSON; STEVE WILLIS; BENYAM YOHANNES; MICHAL ZOOKIN; LIDIA ALDANAY; MARIDEE ALEXANDER; ELSIE AYERS; JACK AYERS; CATHERINE BARBER; LEVELYN BARBER; MATTHEW BEAUCHAMP; SEDRA BECKMAN; THOMAS BEEM; EMMA RUTH BELL; NATHANIA BELL; PAMELA BERTRAND; VICKI BEVERLY; FRED BLACKINGTON; BARBARA BLAIR; MICHELLE BOYCE; NORANNE BRUMAGEN; HOWARD BUGHER; ROBERT BUSTER; WINIFRED CARTER; CODELL CHAVIS; BONNIE CLARK; KIP COOPER; MICHEL COOPER; CHRISTA

COYNE; NIKKI DAWSON; LOU DECKER; PETER DEMPSEY; MARIA DOMINGUEZ; CAROLYN DONAHUE; LAWRENCE DONAHUE; CONRAD DUPONT; DEBORAH ESTEEN; LUPE EVANGELIST; KAREN FANELLI; LAFONDA FLORES; MADELINE FOSTER; ELOISE FREEMAN; ELLAMAE GAINES; LEAH GIRMA; ANTONIO GONZALES; FRANCISCO GONZALES; RICHARD GREEN; ISABEL GRIJALVA; JAMES HAMILTON; BRENDA HARMAN; DONALD HARMAN; SUSAN HENNING; JOSE HERNANDEZ; MARIE HOEG; JAMES H. MCAVOY; MARGUARITE M. MCAVOY; WILLIAM DEHAVEN; VELOY E. BURTON; SHIRLEY CARR; MARY DOMINGUEZ; CAMILLE HOWEY; LAVADA SHIPERS; JANNIE SMITH; MILDRED J. TWEEDY; KATHERINE HOLZHAUER; ALICIA HOSKINSON; GREG HOUCK; DIONNE JENKINS; JOHN JULIAN; WILLIAM KADER; MARY ELLEN KAISER; VASILIKI KALKANTZAKOS; WILLIAM KEELER; ROBERT KELLAR; SHIRLEY KELLAR; MELANIE KEPPEL; ANITA KINCHEN; PETER KLAS; LINDA KOBIGE; LINDA KORSCHINOWSKI; DURANGO LANE; JUNE LANGER; NANCY LAPA; EDWARD LEVINE; MERSEY LINDSEY; ZOLMAN LITTLE; STEVE LYONS; MARSENE MAKSYMOWSKI; PAT MARINO; BILLIE MATHEWS; KRISTINE MAYEDA; CARMEN MCCALL; MICHAEL MCCOY; ANNETTE MEDLAND; JOSPEHINE MOLINA; LEN MONACO; RACHEL MONTOYA; THEODORE MORRISON; XUAN MAI NGO; JACQUELINE NOVAK; FAITH O'BRIEN; DENISE ORR; JAVIER

PACHECO; ELI PINSONAULT; FLORENCE PINSONAULT; STEVE POKRES; TIMOTHY PRICE; STEVEN RAUSCH; CLIFTON ROLLINS; JOHN ROMERO; JEAN ROSE; RONALD RUTHER; JUAN SALAZAR; PRISCILLA SALDANA; BUDDIE SALSBURY; BERNICE SANDERS; DANNY SCALICE; CARL SMITH; VICKIE SMITH; WILLIAM SNEDEKER; EDWARD SOLIS; MARY SOLIZ; ROGER SOWINSKI; CYNTHIA SPENCER; STEPHEN STAGG; TROY STATEN; LINDA STEINER; GWEN STONE; PHAEDRA SUNDAY; CLARENCE TAYLOR; CATHERINE THOMPSON; MARGRETT THOMPSON; VERNON THOMPSON; DAVID TOMLIN; VON TRIMBLE; CHUONG VAN TRONG; JOHN VICCIA; STEVEN VIG; JANET VOPINEK; KATHY WALENT; LINDA WALKER; SHIRLEY WASHINGTON; MARY WENTWORTH; BETTY WERNER; SALLY WEST; DEE LOUISE WHITNEY; SHIRLEY WOODS; TONY YUTYATAT; CATALINA ZAFRA; METRO ZAMITO; CHRISTINA ZEPEDA; ANDREW ZIELINSKI; CAROLYN ARMSTRONG; BETTY BRADLEY; CHARLEEN DAVIS-SHAW; REBECCA DAY; DION DRAUGH; VINCENZO ESPOSITO,

Real Parties in Interest.

Tami D. Cowden, Esq., NBN 8994
Eric Swanis, Esq., NBN 6840
Jason K. Hicks, Esq., NBN 13149
GREENBERG TRAURIG, LLP
10845 Griffith Peak Drive, Ste. 600
Las Vegas, Nevada 89135
Telephone (702) 792-3773
Facsimile (702) 792-9002
Email: cowdent@gtlaw.com
swanise@gtlaw.com
hicksja@gtlaw.com

Brian Rubenstein, Esq.
Admitted Pro Hac Vice
GREENBERG TRAURIG, LLP
1717 Arch Street, Suite 400
Philadelphia, Pennsylvania 19103
Telephone: (215) 988-7864
Email: rubensteinb@gtlaw.com

PHILIP M. HYMANSON
Nevada Bar No. 2253
HENRY J. HYMANSON
Nevada Bar No. 14381
HYMANSON & HYMANSON
8816 Spanish Ridge Avenue
Las Vegas, Nevada 89148
Telephone: (702) 629-3300
Facsimile: (702) 629-3332
Email: Phil@HymansonLawNV.com
Hank@HymansonLawNV.com

Attorneys for Petitioners

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I	APP0014-29	9/27/18	Complaint filed in Sossy Abadjian, et al. v. Teva Parenteral Medicines, Inc., et al.
I	APP0001-13	7/26/18	Complaint filed in Yvette Adams, et al. v. Teva Parenteral Medicines, Inc., et al.
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II	APP0362-434	6/27/19	Plaintiffs' Opposition to Defendants' Motion to Dismiss filed in Maureen Bridges, et al. v. Teva Parenteral Medicines, Inc., et al.
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CERTIFICATE OF SERVICE

Pursuant to NRAP 25.1 certify that I am an employee of GREENBERG TRAURIG, LLP, that in accordance therewith, on April 17, 2020, I caused a copy of ***Petitioner's Appendix*** to be served via U.S. Mail, first class postage prepaid, and via the 8th Judicial District Court's e-service system, to

Glen J. Lerner, Esq. GLEN LERNER INJURY ATTORNEYS 4795 South Durango Drive Las Vegas, NV 89147 *Attorneys for Real Parties in Interest*	Peter C. Wetherall, Esq. WETHERALL GROUP, LTD. 9345 w. Sunset Rd., Ste. 100 Las Vegas, NV 89148 *Attorneys for Real Parties in Interest*
With courtesy copies via email (pursuant to March 20, 2020 order of the Chief Judge of the EDJC that courtesy copies be submitted via email) :	
Hon. Nancy Allf Eighth Judicial District Court Clark County, Nevada Regional Justice Center Department 27 200 Lewis Avenue Las Vegas, NV 89155 Hon. Trevor Atkins Eighth Judicial District Court Clark County, Nevada Regional Justice Center Department 8 200 Lewis Avenue Las Vegas, NV 89155, and	Hon. Jim Crockett Eighth Judicial District Court Clark County, Nevada Regional Justice Center Department 24 200 Lewis Avenue Las Vegas, NV 89155

/s/ Andrea Lee Rosehill
An Employee of Greenberg Traurig LLP

...d onset of peak drug effect. Most adult patients require maintenance ... 3 mg/kg/h or higher. Dosages of propofol should be reduced in patients who have received large dosages ... narcotics. Conversely, the propofol dosage requirement may be reduced by adequate management of pain with analgesic agents. As with other sedative medications, there is interpatient variability in dosage requirements, and these requirements may change with time. (See DOSAGE GUIDE.) **EVALUATION OF LEVEL OF SEDATION AND ASSESSMENT OF CNS FUNCTION SHOULD BE CARRIED OUT DAILY THROUGHOUT MAINTENANCE TO DETERMINE THE MINIMUM DOSE OF PROPOFOL REQUIRED FOR SEDATION.** (SEE Clinical Trials, ICU Sedation.) Bolus administration of 10 or 20 mg should only be used to rapidly increase depth of sedation in patients where hypotension is not likely to occur. Patients with compromised myocardial function, intravascular volume depletion, or abnormally low vascular tone (e.g., sepsis) may be more susceptible to hypotension. (See PRECAUTIONS.)

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

SUMMARY OF DOSAGE GUIDELINES - Dosages and rates of administration in the following table should be individualized and titrated to clinical response. Safety and dosage requirements in pediatric patients have only been established for induction and maintenance of anesthesia. For complete dosage information, see CLINICAL PHARMACOLOGY - Individualization of Dosage.

INDICATION	DOSAGE AND ADMINISTRATION
Induction of General Anesthesia	
	Healthy Adults Less Than 55 Years of Age: 40 mg every 10 seconds until induction onset (2 to 2.5 mg/kg)
	Elderly, Debilitated, or ASA III/IV Patients: 20 mg every 10 seconds until induction onset (1 to 1.5 mg/kg)
	Cardiac Anesthesia: 20 mg every 10 seconds until induction onset (0.5 to 1.5 mg/kg)
	Neurosurgical Patients: 20 mg every 10 seconds until induction onset (1 to 2 mg/kg)
	Pediatric - Healthy, 3 years of age or older: 2.5 to 3.5 mg/kg administered over 20-30 seconds
Maintenance of General Anesthesia: Infusion	
	Healthy Adults Less Than 55 Years of Age: 100 to 200 mcg/kg/min (6 to 12 mg/kg/h)
	Elderly, Debilitated, or ASA III/IV Patients: 50 to 100 mcg/kg/min (3 to 6 mg/kg/h)
	Cardiac Anesthesia: Most patients require:
	Primary Propofol with Secondary Opioid - 100-150 mcg/kg/min
	Low Dose Propofol with Primary Opioid - 50-100 mcg/kg/min (See CLINICAL PHARMACOLOGY Table 4)
	Neurosurgical Patients: 100 to 200 mcg/kg/min (6 to 12 mg/kg/h)
	Pediatric - Healthy, 3 yrs of age or older: 125 to 300 mcg/kg/min (7.5 to 18 mg/kg/h).
Maintenance of General Anesthesia: Intermittent Bolus	
	Healthy Adults Less Than 55 Years of Age: Increments of 20 to 50 mg as needed.
Initiation of MAC Sedation	
	Healthy Adults Less Than 55 Years of Age: Slow infusion or slow injection techniques are recommended to avoid apnea or hypotension. Most patients require an infusion of 100 to 150 mcg/kg/min (6 to 9 mg/kg/h) for 3 to 5 minutes or a slow injection of 0.5 mg/kg over 3 to 5 minutes followed immediately by a maintenance infusion.
	Elderly, Debilitated, Neurosurgical, or ASA III/IV Patients: Most patients require dosages similar to healthy adults. Rapid boluses are to be avoided. (See WARNINGS.)
Maintenance of MAC Sedation	
	Healthy Adults Less Than 55 Years of Age: A variable rate infusion technique is preferable over an intermittent bolus technique. Most patients require an infusion of 25 to 75 mcg/kg/min (1.5 to 4.5 mg/kg/h) or incremental bolus doses of 10 mg or 20 mg.
	In Elderly, Debilitated, Neurosurgical, or ASA III/IV Patients: Most patients require 80% of the usual adult dose. A rapid (single or repeated) bolus dose should not be used. (See WARNINGS.)
Initiation and Maintenance of ICU Sedation in Intubated, Mechanically Ventilated	
	Adult Patients - Because of the lingering effects of previous anesthetic or sedative agents, in most patients the initial infusion should be 5 mcg/kg/min (0.3 mg/kg/h) for at least 5 minutes. Subsequent increments of 5 to 10 mcg/kg/min (0.3 to 0.6 mg/kg/h) over 5 to 10 minutes may be used until desired level of sedation is achieved. Maintenance rates of 5 to 50 mcg/kg/min (0.3 to 3 mg/kg/h) or higher may be required. **Evaluation of level of sedation and assessment of CNS function should be carried out daily throughout maintenance to determine the minimum dose of propofol required for sedation.**
	The tubing and any unused portions of propofol injectable emulsion should be discarded after 12 hours because propofol injectable emulsion contains no preservatives and is capable of supporting growth of microorganisms. (See WARNINGS, and DOSAGE AND ADMINISTRATION.)

Compatibility and Stability: Propofol injectable emulsion should not be mixed with other therapeutic agents prior to administration.

Dilution Prior to Administration: Propofol injectable emulsion is provided as a ready to use formulation. However, should dilution be necessary, it should only be diluted with 5% dextrose injection and it should not be diluted to a concentration less than 2 mg/mL because it is an emulsion in that form. It has been shown to be more stable when in contact with glass than with plastic (95% potency after 2 hours of running infusion in glass).

Co-Administration with Other Fluids: Compatibility of propofol injectable emulsion with the co-administration of blood/serum/plasma has not been studied. (See WARNINGS.) Propofol injectable emulsion has been shown to be compatible when administered with the following intravenous fluids:

Dextrose Injection (5%)
Lactated Ringers and Dextrose (5%)
Dextrose (5%) and Sodium Chloride (0.45%) Injection
Dextrose (5%) and Sodium Chloride (0.2%) Injection

Handling Procedures

Inspect:
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Clinical experience with the use of in-line filters and propofol injectable emulsion during anesthesia or ICU/MAC sedation is limited. Propofol injectable emulsion should only be administered through a filter with a pore size of 5 microns or greater unless it has been demonstrated that the filter does not restrict the flow of propofol injectable emulsion and/or cause the breakdown of the emulsion. Filters should be used with caution and where clinically indicated. Continuous monitoring is necessary due to the potential for restricted flow and/or breakdown of the emulsion.

Do not use if there is evidence of separation of the phases of the emulsion.

Misuse in cases of self-administration of propofol injectable emulsion by health care professionals have been reported, including some fatalities. (See WARNING: ABUSE AND DEPENDENCE.)

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STRICT ASEPTIC TECHNIQUE MUST ALWAYS BE MAINTAINED DURING HANDLING. PROPOFOL INJECTABLE EMULSION IS A SINGLE-USE PARENTERAL PRODUCT WHICH CONTAINS SODIUM METABISULFITE (0.25 MG/ML) TO RETARD THE RATE OF GROWTH OF MICROORGANISMS IN THE EVENT OF ACCIDENTAL EXTRINSIC CONTAMINATION. HOWEVER, PROPOFOL INJECTABLE EMULSION CAN STILL SUPPORT THE GROWTH OF MICROORGANISMS AS IT IS NOT AN ANTIMICROBIALLY PRESERVED PRODUCT UNDER USP STANDARDS. ACCORDINGLY, STRICT ASEPTIC TECHNIQUE MUST STILL BE ADHERED TO. DO NOT USE IF CONTAMINATION IS SUSPECTED. DISCARD UNUSED PORTIONS AS DIRECTED WITHIN THE REQUIRED TIME LIMITS (SEE DOSAGE AND ADMINISTRATION, HANDLING PROCEDURES). THERE HAVE BEEN REPORTS IN WHICH FAILURE TO USE ASEPTIC TECHNIQUE WHEN HANDLING PROPOFOL INJECTABLE EMULSION WAS ASSOCIATED WITH MICROBIAL CONTAMINATION OF THE PRODUCT AND WITH FEVER, INFECTIONS/SEPSIS, OTHER LIFE-THREATENING ILLNESS, AND/OR DEATH.

Guidelines for Aseptic Technique for General Anesthesia/MAC Sedation

Propofol injectable emulsion should be prepared for use just prior to initiation of each individual anesthetic/sedative procedure. The vial rubber stopper should be disinfected using 70% isopropyl alcohol. Propofol injectable emulsion should be drawn into sterile syringes immediately after vials are opened. When withdrawing propofol injectable emulsion from vials, a sterile vent spike should be used. Administration should commence promptly and be completed within 6 hours after the vials have been pierced.

Propofol injectable emulsion should be prepared for single patient use only. Any unused portions of propofol injectable emulsion, reservoirs, dedicated administration tubing and/or solutions containing propofol injectable emulsion must be discarded at the end of the anesthetic procedure or at 6 hours, whichever occurs sooner. The I.V. line should be flushed every 6 hours and at the end of the anesthetic procedure to remove residual propofol injectable emulsion.

Guidelines for Aseptic Technique for ICU Sedation

Propofol injectable emulsion should be prepared for single patient use only. When propofol injectable emulsion is administered directly from the vial, strict aseptic technique must be followed. The vial rubber stopper should be disinfected using 70% isopropyl alcohol. A sterile vent spike and sterile tubing must be used for administration of propofol injectable emulsion. As with other lipid emulsions, the number of I.V. line manipulations should be minimized. Administration should commence promptly and must be completed within 12 hours after the vial has been spiked. The tubing and any unused portions of propofol injectable emulsion must be discarded after 12 hours.

If propofol injectable emulsion is transferred to a syringe or other container prior to administration, the handling procedures for general anesthesia/MAC sedation should be followed, and the product should be discarded and administration lines changed after 6 hours.

HOW SUPPLIED

Propofol injectable emulsion is available in ready-to-use 20 mL vials, 50 mL infusion vials, and 100 mL infusion vials containing 10 mg/mL of propofol.

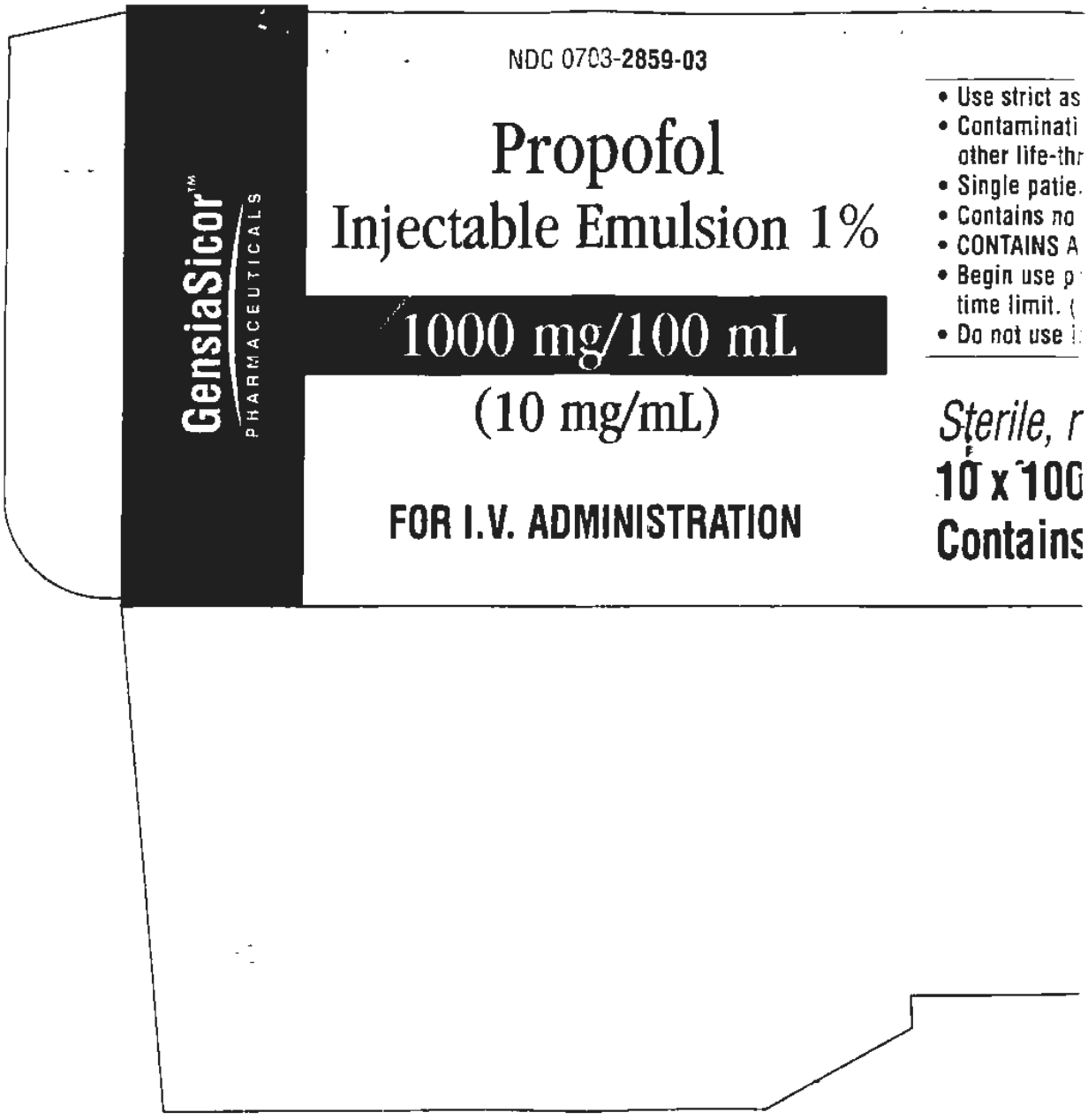
Vials:

NDC Number	Propofol	Available Packaging
0703-2630-04	20 mL vial	25 vials/shelf tray
0703-2634-05	50 mL infusion vial	20 vials/shelf tray
0703-2631-03	100 mL infusion vial	10 vials/shelf tray

Propofol undergoes oxidative degradation in the presence of oxygen, and is, therefore, packaged under nitrogen to eliminate this degradation path. Store between 4°-22°C (40°-72°F). Do not freeze. Shake well before use.

R_x only

Issued: December 1996
Gensia Sicor Pharmaceuticals, Inc.
Irvine, CA 92618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PHARMACEUTICALS
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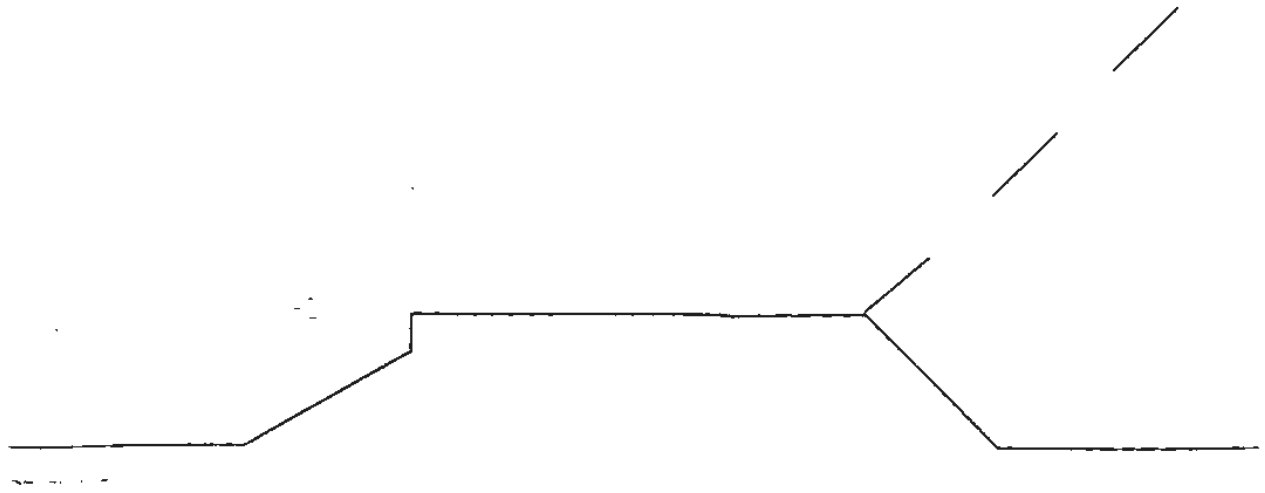
ADMINISTRATION

- Use strict aseptic tech..ique.
- Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
- Single patient use.
- Contains no preservative.
- CONTAINS A SULFITE: microbial growth may still be supported.
- Begin use promptly after opening. Discard within specified time limit. (See package insert.)
- Do not use if contamination is suspected.

Sterile, nonpyrogenic

10 x 100 mL single-patient infusion vial

Contains a Sulfite



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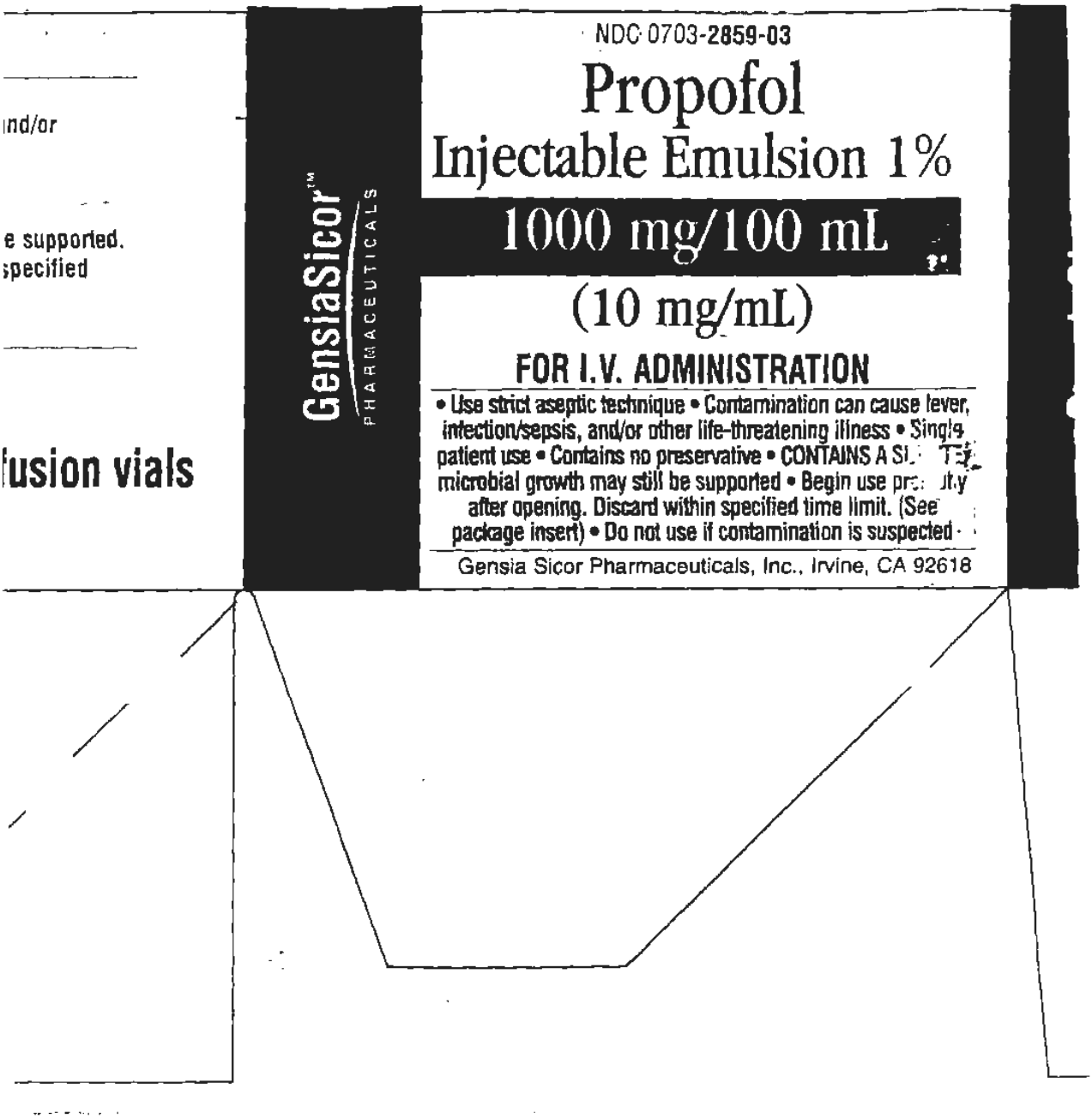
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PHARMACEUTICALS
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(10 mg/mL)
FOR I.V. ADMINISTRATION
• Use strict aseptic technique • Contamination can cause fever, infection/sepsis, and/or other life-threatening illness • Single patient use • Contains no preservative • CONTAINS A SU T microbial growth may still be supported • Begin use pr ly after opening. Discard within specified time limit. (See package insert) • Do not use if contamination is suspected
Gensia Sicor Pharmaceuticals, Inc., Irvine, CA 92618

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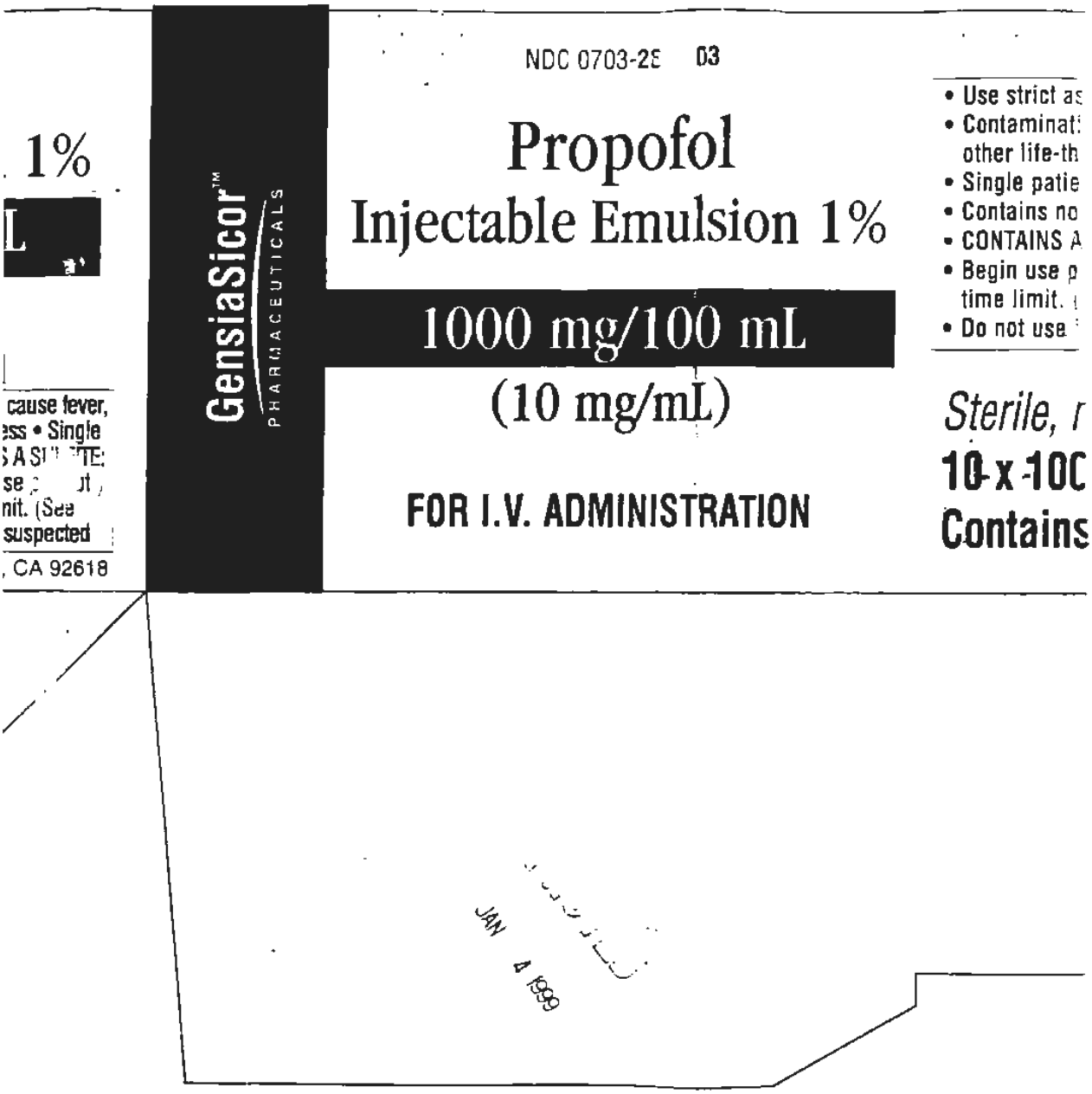
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- Use strict aseptic technique.
- Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
- Single patient use.
- Contains no preservative.
- CONTAINS A SULFITE; microbial growth may still be supported.
- Begin use promptly after opening. Discard within specified time limit. (See package insert.)
- Do not use if contamination is suspected.

Sterile, nonpyrogenic

10 x 100 mL single-patient infusion vials

Contains a Sulfite

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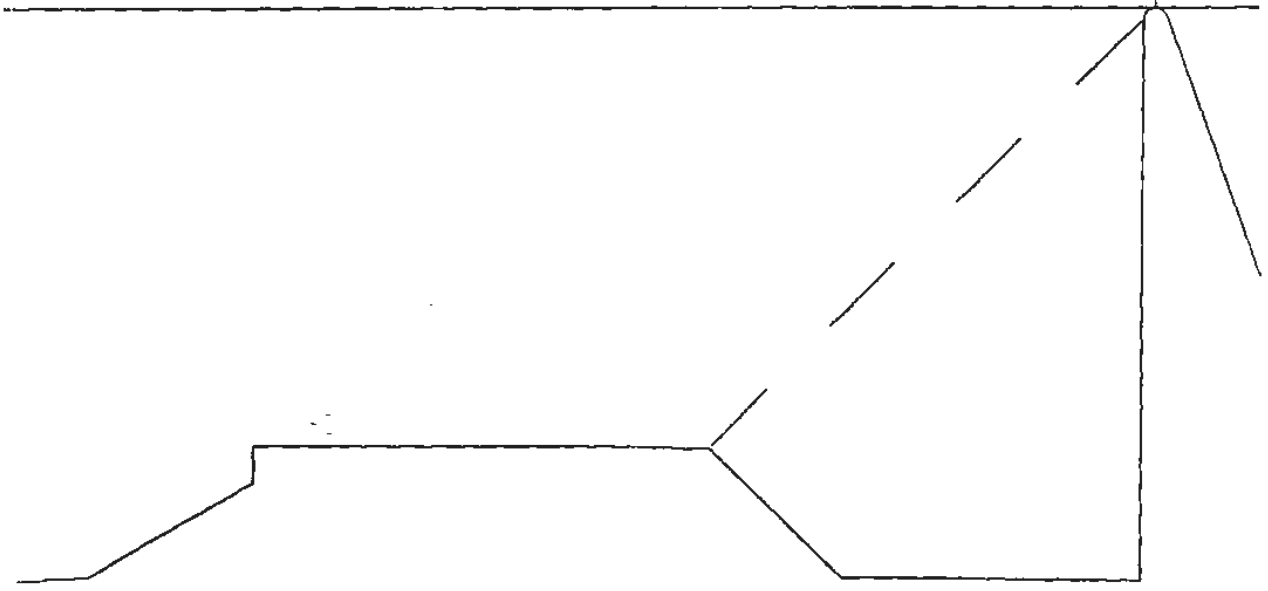

020

APP0974

s, and/or

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hin specified

infusion vials

- Use strict aseptic technique.
- Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
- Single patient use.
- Contains no preservative.
- CONTAINS A SULFITE; microbial growth may still be supported.
- Begin use promptly after opening. Discard within specified time limit. (See package insert.)
- Do not use if contamination is suspected.

SHAKE WELL BEFORE USE.

Usual Dosage: See insert.

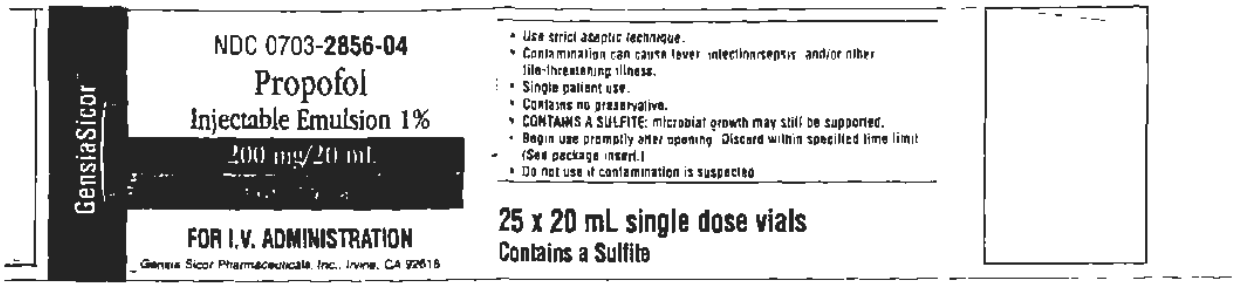
Each mL contains: propofol (10 mg), soybean oil (100 mg), glycerol (22.5 mg), egg yolk phospholipid (12 mg) and **SODIUM METABISULFITE** (0.25 mg); with sodium hydroxide to adjust pH to 4.5-6.4.

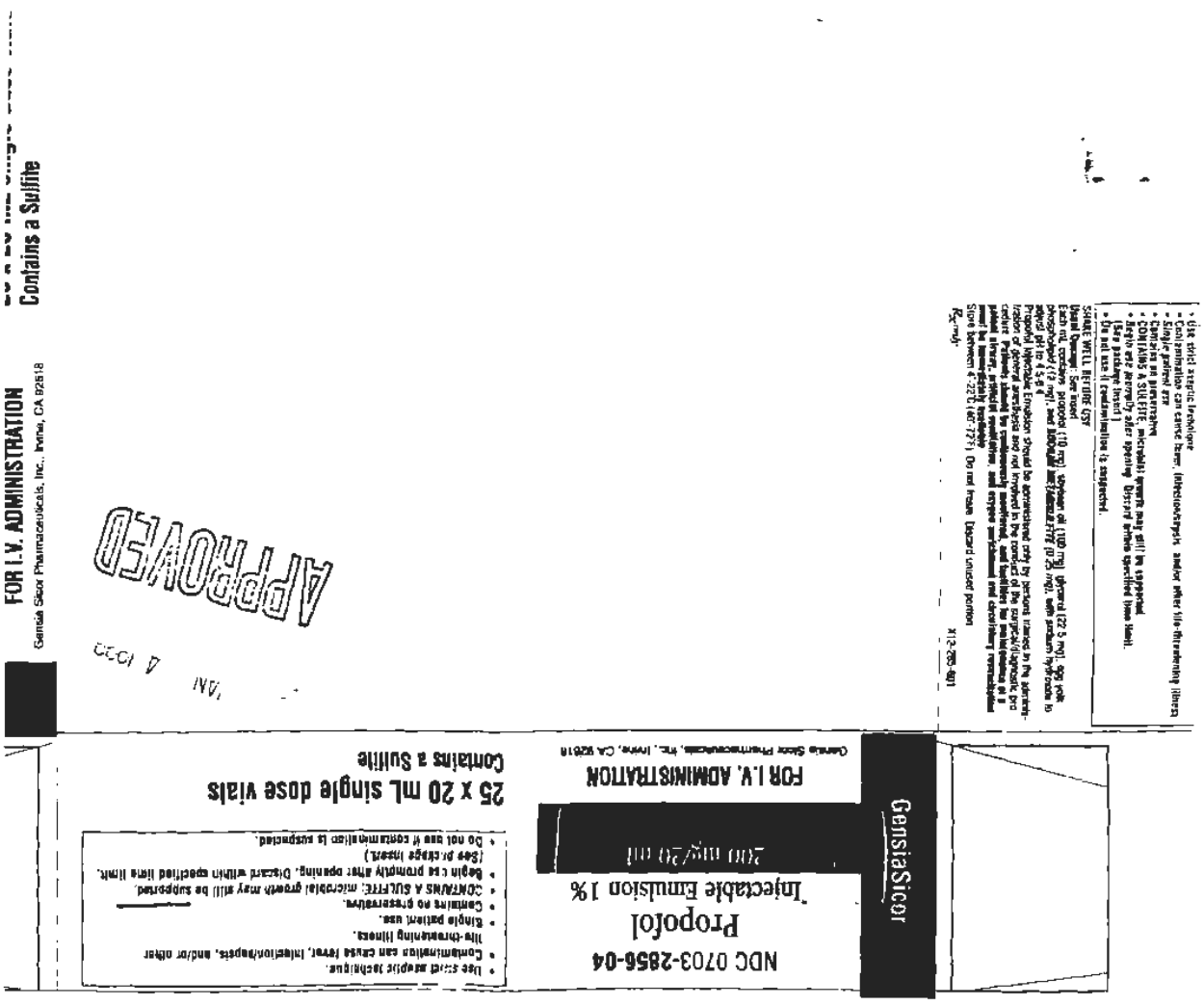
Propofol Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. ***Patients should continuously monitored and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available.***

Store between 4°-22°C (40°-72°F). Do not freeze. Discard unused portion.

Rx only

X12-285-901


GensiaSicor
NDC 0703-2856-04
Propofol
Injectable Emulsion 1%
200 mg/20 mL
FOR I.V. ADMINISTRATION
Gensia Sicor Pharmaceuticals, Inc., Irvine, CA 92618
• Use strict aseptic technique.
• Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
• Single patient use.
• Contains no preservative.
• CONTAINS A SULFITE: microbial growth may still be supported.
• Begin use promptly after opening. Discard within specified time limit (See package insert.)
• Do not use if contamination is suspected
25 x 20 mL single dose vials
Contains a Sulfite

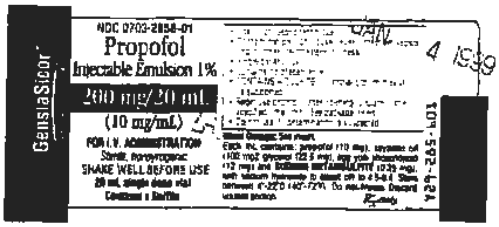

GensiaSicor
NDC 0703-2856-04
Propofol
Injectable Emulsion 1%
200 mg/20 mL
FOR I.V. ADMINISTRATION
Gensia Sicor Pharmaceuticals, Inc., Irvine, CA 92618
25 x 20 mL single dose vials
Contains a Sulfite
• Use strict aseptic technique.
• Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
• Single patient use.
• Contains no preservative.
• CONTAINS A SULFITE: microbial growth may still be supported.
• Begin use promptly after opening. Discard within specified time limit (See package insert.)
• Do not use if contamination is suspected.
FOR I.V. ADMINISTRATION
Gensia Sicor Pharmaceuticals, Inc., Irvine, CA 92618
Contains a Sulfite
APPROVED

022

APP0976

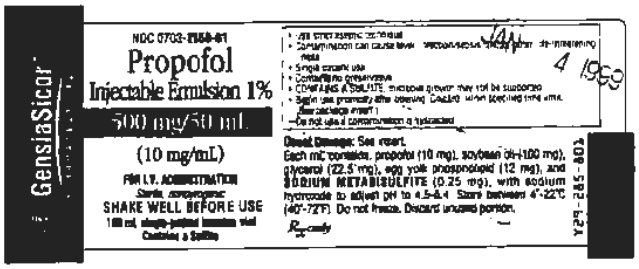
Container Label - NDC 0703-2856-04

(Part No. Y29-285-601)
200 mg/20 mL vial



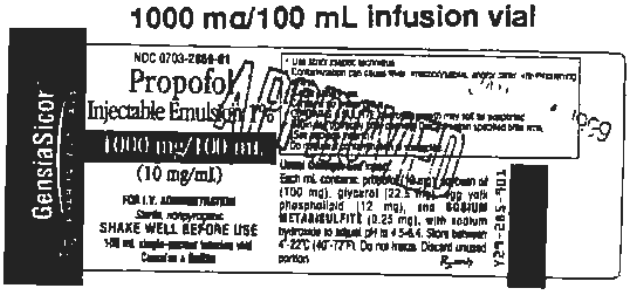
Container Label - NDC 0703-2858-09

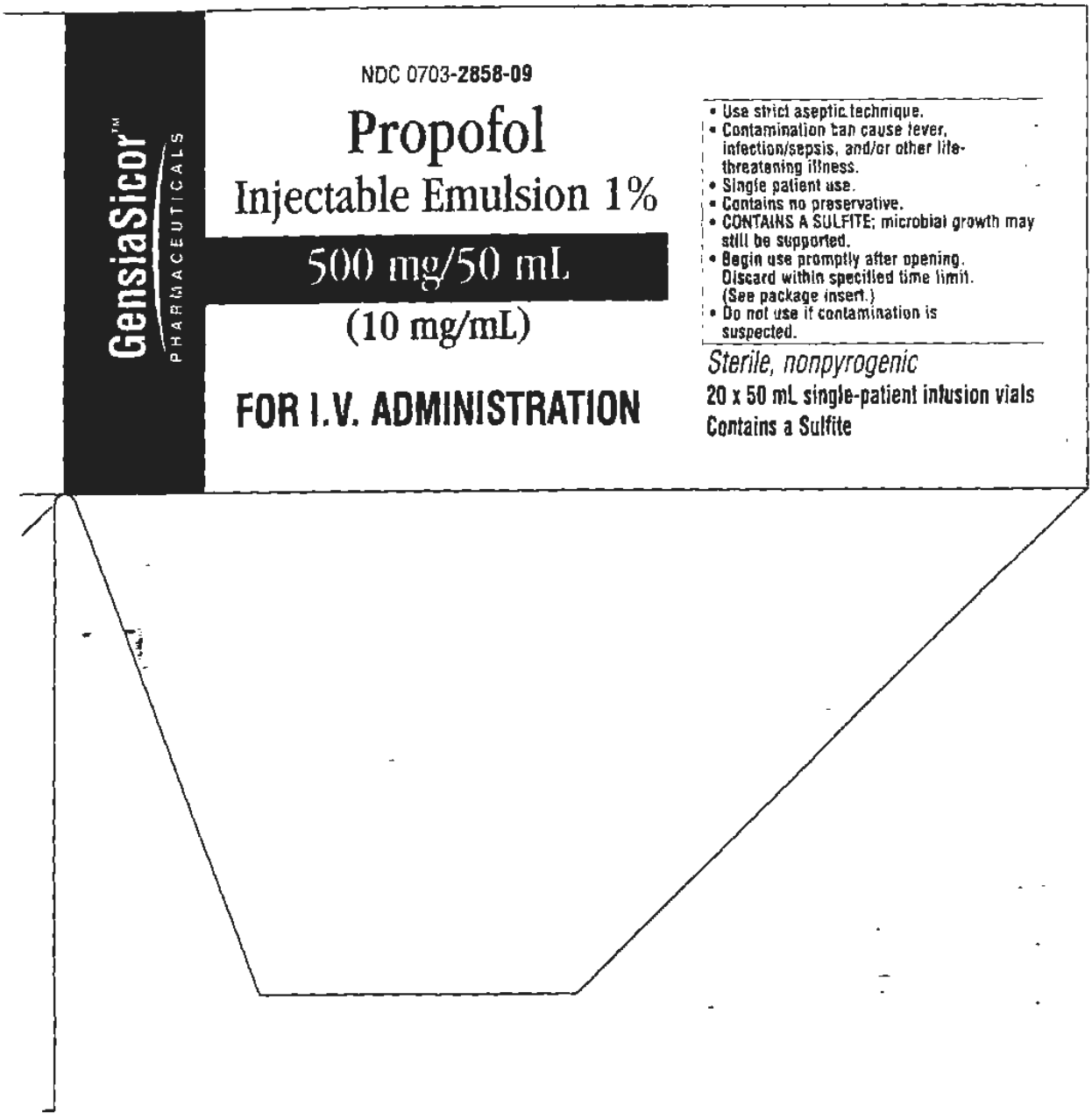
(Part No. Y29-285-801)
500 mg/50 mL infusion vial



Container Label - NDC 0703-2859-03

(Part No. Y29-285-901)
1000 mg/100 mL infusion vial




GensiaSicor™
PHARMACEUTICALS
NDC 0703-2858-09
Propofol
Injectable Emulsion 1%
500 mg/50 mL
(10 mg/mL)
FOR I.V. ADMINISTRATION
• Use strict aseptic technique.
• Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
• Single patient use.
• Contains no preservative.
• CONTAINS A SULFITE; microbial growth may still be supported.
• Begin use promptly after opening. Discard within specified time limit. (See package insert.)
• Do not use if contamination is suspected.
Sterile, nonpyrogenic
20 x 50 mL single-patient infusion vials
Contains a Sulfite

025

APP0979

NDC 0703-2858-09

Propofol

Injectable Emulsion 1%

500 mg/50 mL

(10 mg/mL)

FOR I.V. ADMINISTRATION

GensiaSicor Pharmaceuticals, Inc., Irvine, CA 92618

JAN 4 1999

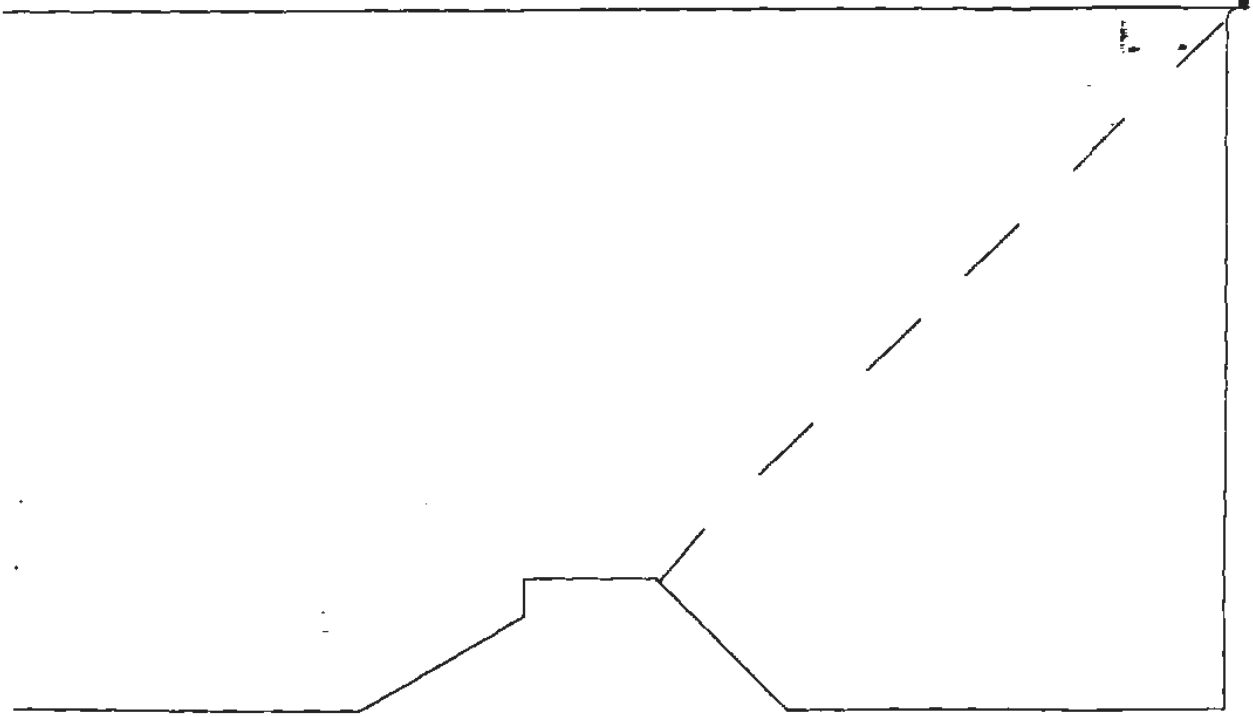
APPROVED

- Use strict aseptic technique.
- Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
- Single patient use.
- Contains no preservative.
- CONTAINS A SULFITE: microbial growth may still be supported.
- Begin use promptly after opening. Discard within specified time limit. (See package insert.)
- Do not use if contamination is suspected.

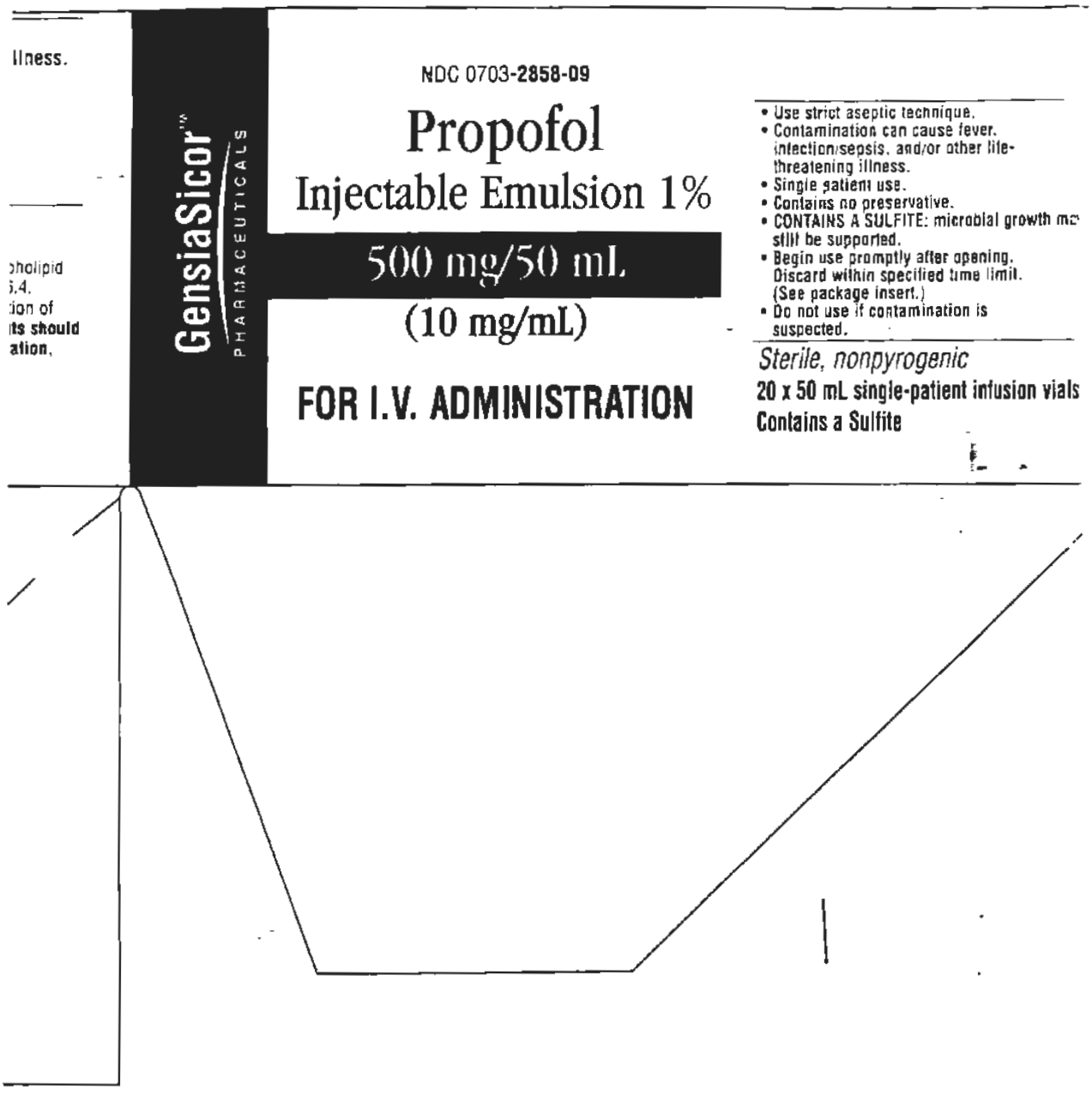
Sterile, nonpyrogenic

20 x 50 mL single-patient infusion vials

Contains a Sulfite



026


lIness.
GensiaSicor
PHARMACEUTICALS
NDC 0703-2858-09
Propofol
Injectable Emulsion 1%
500 mg/50 mL
(10 mg/mL)
FOR I.V. ADMINISTRATION
• Use strict aseptic technique.
• Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.
• Single patient use.
• Contains no preservative.
• CONTAINS A SULFITE: microbial growth may still be supported.
• Begin use promptly after opening. Discard within specified time limit. (See package insert.)
• Do not use if contamination is suspected.
Sterile, nonpyrogenic
20 x 50 mL single-patient infusion vials
Contains a Sulfite

027

APP0981

- **Use strict aseptic technique.**
- **Contamination can cause fever, infection/sepsis, and/or other life-threatening illness.**
- **Single patient use.**
- **Contains no preservative.**
- **CONTAINS A SULFITE; microbial growth may still be supported.**
- **Begin use promptly after opening. Discard within specified time limit. (See package insert.)**
- **Do not use if contamination is suspected.**

SHAKE WELL BEFORE USE.

Usual Dosage: *See insert.*

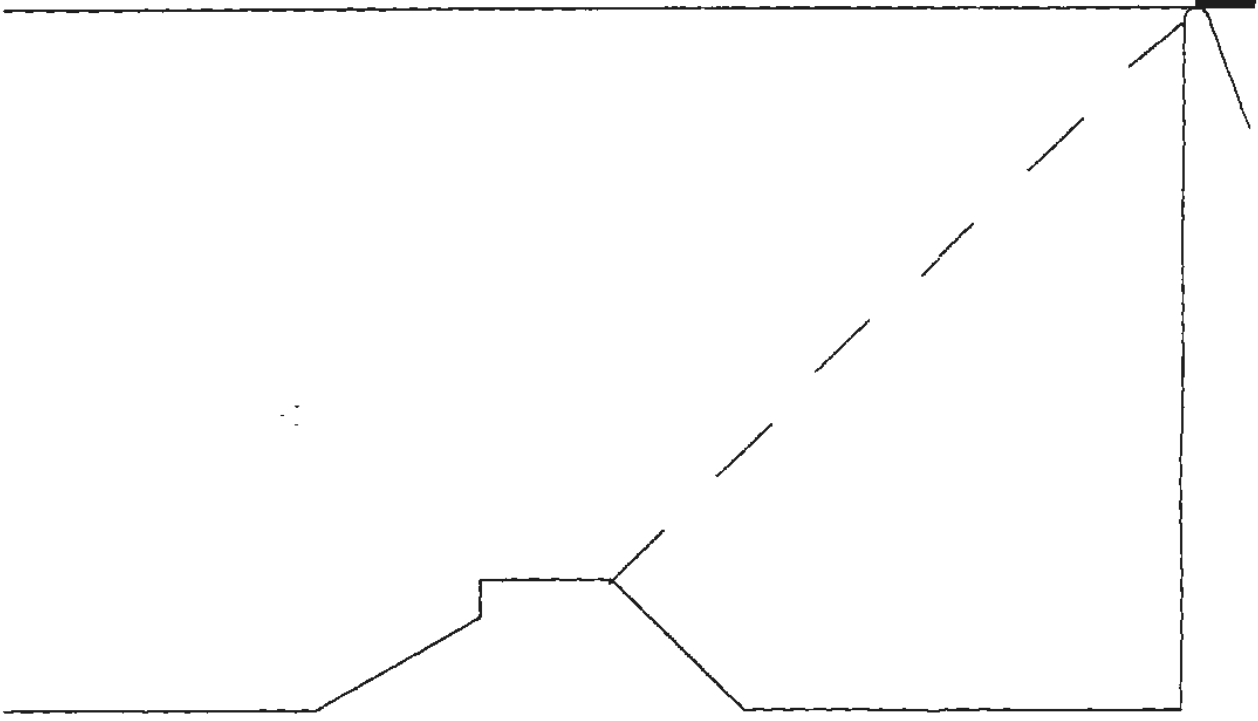
Each mL contains: propofol (10 mg), soybean oil (100 mg), glycerol (22.5 mg), egg yolk phospholipid (12 mg) and **SODIUM METABISULFITE** (0.25 mg); with sodium hydroxide to adjust pH to 4.5-6.4.

Propofol Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure. **Patients should be continuously *monitored* and facilities for maintenance of a patent airway, *artificial* ventilation, and oxygen enrichment and *circulatory* resuscitation must be immediately available.**

Store between 4°-22°C (40°-72°F). Do not freeze. Discard unused portion.

Rx only

Gensia Sicor Pharmaceuticals, Inc., Irvine, CA 92618 X12-285-801



028

APP0982

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. 2

2. ANDA #75-102

3. NAME AND ADDRESS OF APPLICANT
Gensia Sicor Pharmaceuticals
17 Hughes
Irvine, CA 92718-1902

4. LEGAL BASIS FOR ANDA SUBMISSION
Generic version of Zeneca, Ltd., Diprivan® (NDA 19-627).
Patent certification and exclusivity statement are provided (pp 013-017).

5. SUPPLEMENT(s) N/A

6. ESTABLISHED NAME
Propofol Injectable Emulsion (With 0.025% Sodium Metabisulfite)

7. PROPRIETARY NAME
N/A

8. SUPPLEMENT(s) PROVIDE(s) FOR Original ANDA

9. AMENDMENTS AND OTHER DATES

Firm		FDA	
Orig. submission	3/31/97	Acknowledgment letter	5/8/97
Amendment	5/20/97		
		Micro review	9/17/97
		Deficiency letter	10/22/97
Amendment (Bio)	12/11/97		
Amendment	12/3/97		

Change to 0.025% Sodium Metabisulfite

Amendment	1/16/98		
New correspondence	2/11/98		
New correspondence	4/13/98		
New correspondence	5/27/98	Bio review (Final)	6/23/98
New correspondence	6/30/98		
New correspondence	8/10/98		
Amendment	8/24/98	Micro review	10/23/98
Amendment	10/16/98		
Amendment	12/14/98		
New correspondence	12/15/98	Label review	12/21/98
New correspondence	12/28/98		

10. PHARMACOLOGICAL CATEGORY
Anesthetic - is indicated for both induction and/or maintenance of anesthesia as part of a balanced anesthetic technique for inpatient and outpatient surgery.

11. Rx or OTC
℞

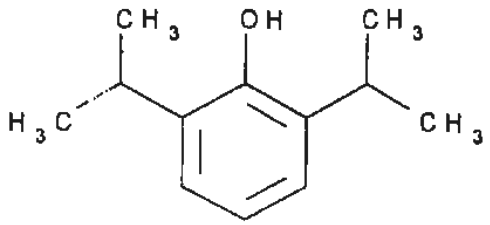
12. RELATED ANDA/DMF(s)

13. DOSAGE FORM
Injection (I.V. Administration)

14. STRENGTH
10 mg/ml

15. CHEMICAL NAME AND STRUCTURE

Propofol
$C_{12}H_{18}O$; M.W. = 178.27



2,6-Diisopropylphenol. CAS [2078-54-8]

Drug substance and drug product are not official USP 23 items.

16. RECORDS AND REPORTS None

17. COMMENTS

a. Application is **satisfactory** for approval
b. Labeling review **ACCEPTABLE**, dated 12/21/98
c. Bio review found **ADEQUATE**, dated 6/23/98
d. Micro review found **ADEQUATE**, dated 10/23/98
d. DMF found **ADEQUATE**, dated 11/17/98
e. Methods validation for drug substance and drug product have been evaluated under ANDA 74-816. Only the sodium metabisulfite assay was tested on this ANDA.
f. Establishment Evaluation Report has been found **ADEQUATE**, dated 12/14/98.
g. ANDA has same manufacturing process as companion ANDA 74-816 (vials).

18. CONCLUSIONS AND RECOMMENDATIONS

APPROVE

19. REVIEWER	DATE COMPLETED
Raymond Brown	December 28, 1998

Page(s) 13

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chemistry Review #2
12/28/98

Page(s) 1

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

10/22/97

Chemistry Comment

#35

1. CHEMIST'S REVIEW NO.1

2. ANDA #75-102

3. NAME AND ADDRESS OF APPLICANT
Gensia Laboratories, Ltd.
19 Hughes
Irvine, CA 92718-1902

4. LEGAL BASIS FOR ANDA SUBMISSION
Generic version of Zeneca, Ltd., Diprivan® (NDA 19-627).
Patent certification and exclusivity statement are provided (pp. 013-017).

U.S. Patent No. 4056635, expired November 1, 1996

5. SUPPLEMENT(s) N/A

6. ESTABLISHED NAME
Propofol Injectable Emulsion 1% (Witt

7. PROPRIETARY NAME
N/A

8. SUPPLEMENT(s) PROVIDE(s) FOR Original ANDA

9. AMENDMENTS AND OTHER DATES

Firm		FDA	
Orig. submission	3/31/97	Acknowledgment letter	5/8/97
		CSO review	4/29/97
		Label review	Pending
Amendment	5/20/97	Bio review	Pending
		Micro review	9/17/97

This review covers submissions dated 3/31/97 and 5/20/97.

10. PHARMACOLOGICAL CATEGORY
Anesthetic - is indicated for both induction and/or maintenance of anesthesia as part of a balanced anesthetic technique for inpatient and outpatient surgery.

11. Rx or OTC
℞

12.

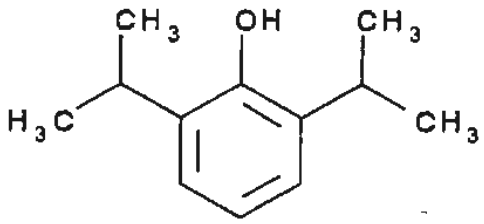
13. DOSAGE FORM
Injection (I.V. Administration)

14. STRENGTH
10 mg/ml

15. CHEMICAL NAME AND STRUCTURE

Propofol

$C_{12}H_{18}O$; M.W. = 178.27



2,6-Diisopropylphenol. CAS [2078-54-8]

Drug substance and drug product are not official USP 23 items.

16. RECORDS AND REPORTS None

17. COMMENTS
a. Application contains **facsimile** CMC deficiencies
b. Labeling **pending** dated.
c. Bio (with found **pending**, dated
d. Micro found **satisfactory**, dated 9/17/97
d. DMF found satisfactory, dated 7/25/97
e. Methods validation for both drug substance and drug is being evaluated under ANDA 74-816, submitted 4/7/97.
f. Establishment Evaluation Request has been submitted to the Division of Compliance, dated 4/30/97.
g. ANDA has same manufacturing process as companion ANDA 74-816 (vials).

18. CONCLUSIONS AND RECOMMENDATIONS

NOT APPROVABLE

19. REVIEWER: Raymond Brown

DATE COMPLETED: July 25, 1997

Page(s) 15

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chemistry Review #1

7/25/97

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

BIOEQUIVALENCE REVIEW(S)

7.1

Propofol Injectable Emulsion
10 mg/mL
ANDA #75-102
Review: Moheb H. Makary
Filename: 75102W.198

Gensia Laboratories
Irvine, CA
Submission Date:
1/16/1998

Addendum to the January 16, 1998 Review

Gensia's formulation for Propofol Injectable Emulsion, 10 mg/mL, contains 0.025% sodium metabisulfite instead of used in the reference product by Zeneca. Therefore, the waiver for the test product should be granted based on CFR 320.24(b)(6) not on CFR 320.22 (b)(1) as stated in the original review (review dated June 23, 1998).

/S/

Moheb H. Makary, Ph.D.
Division of Bioequivalence
Review Branch III

Concur /S/ Date: 12/30/98
Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

Propofol Injectable Emulsion
10 mg/mL
ANDA #75-102
Review: Moheb H. Makary
Filename: 75102W.198

Gensia Laboratories
Irvine, CA
Submission Date:
1/16/1998

Addendum to the January 16, 1998 Review

Gensia's formulation for Propofol Injectable Emulsion, 10 mg/mL, contains 0.025% sodium metabisulfite instead of used in the reference product by Zeneca. Therefore, the waiver for the test product should be granted based on CFR 320.24(b)(6) not on CFR 320.22 (b)(1) as stated in the original review (review dated June 23, 1998).

/S/

Moheb H. Makary, Ph.D.
Division of Bioequivalence
Review Branch III

/S/

Concur:_____ Date: 12/30/98

Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

Mmakary/12-30-98, 75102W.D98

DIVISION REVIEW SUMMARY

ANDA 75-102 **DRUG PRODUCT:** Propofol Injection Emulsion (with 0.025% Sodium Metabisulfite)

FIRM: Gensia Sicor Pharmaceuticals

DOSAGE FORM: Injectable (Intravenous)

STRENGTH(S): 10 mg/mL

cGMP STATEMENT/EIR UPDATE STATUS: Adequate -
An **ESTABLISHMENT EVALUATION REPORT** issued to the Division of Compliance has found to be ADEQUATE, dated 12/14/98.

BIO INFORMATION: Satisfactory -
The Division of Bioequivalence has granted the waiver is pending the acceptance of the new formulation. See bio review dated 6/23/98.

VALIDATION-(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
Adequate -

Methods validation for drug substance and drug product were performed under ANDA 74-816, which used the same methods. Only the sodium metabisulfite assay was tested on ANDA 75-102. See methods validation report dated May 26, 1998.

STABILITY: Satisfactory -
Accelerated (40°C ± 2°C/75 ± 5% RH and Light Box) stability data are provided for lot nos. XP7N314, XP7S302 and XP7S302F1 tested at 1, 2 and 3 month intervals in the final marketed container/closure systems, 20 mL, 50 mL and 100 mL vials respectively. The data are adequate and within the specified limits. Also provided are controlled room temperature (22 ± 2°C and 25 ± 2°C/60 ± 5% RH), tested at 1, 2, 3, 6 and 9 month intervals in the final container/closure systems. The data are within the specified limits. An expiration dating period of 24 month has been granted.

LABELING: Acceptable -
See review of professional labeling conducted by Kuong Lee, concurred by John Grace, dated 12/16/98.

STERILIZATION VALIDATION: Adequate -
See micro review #2, dated 10/23/98.

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OX?) Satisfactory -
Batch nos. XP7N314 NDS lot no. PL-PROP-4) has a theoretical yield of Liters, actual yield consist of Liters.

Drug Master File found **ADEQUATE**, dated 11/17/98.

SIZE OF STABILITY BATCHES - Satisfactory -
Batch no. XP7N314 a theoretical yield of Liters, actual yield consist of .iters. Batch Reconciliation indicates the entire batch was packaged in to sublots, lot no. XP7S302 and XP7S302F1.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY? Satisfactory -

The proposed maximum production batch size is iters, with equipment specified.

RECOMMENDATION:
APPROVE

cc:

Endorsement: 12/8/98

GENSIA
LABORATORIES LTD

December 11, 1997

NDA ORIG. AMENDMENT

N/A 5

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion
(with 0.005% EDTA), 10 mg/mL
Prefilled Syringe ANDA: 75-102

BIOEQUIVALENCY AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing 0.005% Disodium Edetate (EDTA) in the formulation, ANDA 75-102. Reference is also made to the Agency's letter dated November 30, 1997. In accordance with the provisions of Section 314.96 of the Code of Federal Regulations, Title 21, we hereby amend our application to provide the additional information as requested.

Furthermore, pursuant to the Agency's instructions, a copy of the Bioequivalency Deficiency facsimile is provided in this response.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

RECEIVED
DEC 12 1997
GENERIC DRUGS

Enclosure
cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

S:\APP0751C\AMEND\AMEND3.WPD
Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92618 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0095

NOV 30 1997

J. Johnson

4

BIOEQUIVALENCY DEFICIENCIES TO BE PROVIDED TO THE APPLICANT

ANDA: 75-102 APPLICANT:GENSIA

DRUG PRODUCT: Propofol 10 mg/ml prefilled syringes (injectable emulsion)

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiency has been identified.

1. Please measure the globule size distribution in the prefilled syringes for both the test and reference products.

Sincerely yours,

/S/

Rabindra N. Patnaik, Ph.D.
Acting Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

BIOEQUIVALENCY DEFICIENCIES TO BE PROVIDED TO THE APPLICANT

ANDA: 75-102 APPLICANT:GENSIA

DRUG PRODUCT: Propofol 10 mg/ml prefilled syringes (injectable emulsion)

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiency has been identified.

1. Please measure the globule size distribution in the prefilled syringes for both the test and reference products.

Sincerely yours,

/S/

Rabindra N. Patnaik, Ph.D.
Acting Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Propofol Injection, Prefilled Syringe	Gensia Laboratories
10 mg/mL	Irvine, CA
ANDA #75-102	Submission Date:
Reviewer: Moo Park	3/31/97; 5/20/97
Filename: 75102w.397	

Review of a Waiver Request

I. Objectives

Review of Gensia's waiver request for its Propofol Injection, 10 mg/mL in 20 mL prefilled syringe. Reference listed drug product is Zeneca's Diprivan®, 10 mg/mL in 50 mL prefilled syringe.

II. Background

The applicant received a waiver for its Propofol Injection, 10 mg/mL in 20 mL, 50 mL and 100 mL vials (ANDA #74-816; submission date=12/24/96; review date=5/16/97). This ANDA #75-102 is for Propofol Injection, 10 mg/mL in 20 mL prefilled syringe.

III. Comments

1. Propofol Injection is an oil-in-water emulsion. The formulation of the test product is shown below. The formulations of the test and reference formulations are identical.

Test Formulation

Ingredient	Amount mg/mL
Propofol	10
Soybean Oil, USP	100
Glycerin, USP	22.5
Egg Lecithin	12
Sodium Hydroxide	qs to pH 7-8.5
Water for Injection, USP	qs to 1 mL

2. The globule size distribution data of the test and reference drug products submitted were the same submitted for ANDA #74-816 for the injectable emulsion packaged in vials. The firm should measure the globule size distribution in the prefilled syringe formulation for both the test and reference products. Variables such as filling operation into syringes and contact with packaging components may affect the globule size distribution.

3. The waiver of *in vivo* bioequivalence study requirements for the test product is not granted pending the applicant's new globule size distribution data for the test and reference products packaged in syringes.

IV. Deficiency

The globule size distribution data of the test and reference drug products submitted were the same submitted for ANDA #74-816 for the injectable emulsion packaged in vials. The firm should measure the globule size distribution in the prefilled syringes for both the test and reference products.

V. Recommendation

The Division of Bioequivalence does not agree that the information submitted by Gensia demonstrates that its Propofol Injection (with), 10 mg/mL in prefilled syringe, falls under 21 CFR 320.22(b)(1) of the Bioavailability/Bioequivalence Regulations. The submission is incomplete and the waiver of *in vivo* bioequivalence study requirements for the test product is not granted pending the applicant's response to the deficiency.

The firm should be informed of the deficiency and recommendation.

/S/

Moo Park, Ph.D.
Review Branch III
The Division of Bioequivalence

RD INITIALED RMHATRE
FT INITIALED RMHATRE

/S/ 7/9/97

Concur: /S/ Date: 8/1/97

Nicholas Fleischer, Ph.D.
Director
Division of Bioequivalence

File history: Draft (7/2/97); Final (7/8/97)

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

MICROBIOLOGY REVIEW(S)

OFFICE OF GENERIC DRUGS, HFD-640
Microbiologists Review #1
September 15, 1997

A. 1. ANDA 75-102

APPLICANT Gensia Laboratories, LTD.
19 Hughes
Irvine CA 92718-1902

2. PRODUCT NAMES: **Propofol Injectable Emulsion (with 0.005% EDTA)**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10 mg/mL Emulsion, 200 mg/20 mL Pre-Filled Syringes, Intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Hypnotic Agent (Sedative)

B. 1. DATE OF INITIAL SUBMISSION: **March 31, 1997**
Subject of this Review **(Received April 1, 1997)**

2. DATE OF AMENDMENT: None
3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: 9/8/97

C. REMARKS: The subject drug product is filled into 20 mL glass syringes and terminally sterilized at the Irvine CA pharmaceutical manufacturing facility.

D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. The specific comments are provided in "E. Review Notes".

/S/ 9/16/97
Andrea S. High, Ph. D.

cc:

9/17/97

-102

050

APP1004

Page(s) 4

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Micro Review #1

9/15/97

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

ADMINISTRATIVE DOCUMENTS

Verified 12/30/98 Quality

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: ANDA 75102/000
Stamp: 01-APR-1997 Regulatory Due:
Applicant: GENSIA LABS
19 HUGHES
IRVINE, CA 926181902

Priority: Org Code: 600
Action Goal: District Goal: 01-JUN-1998
Brand Name:
Established Name: PROPOFOL
Generic Name:
Dosage Form: INJ (INJECTION)
Strength: 10MG/ML

FDA Contacts: K. SHERROD (HFD-617) 301-827-5849 , Project Manager
B. ARNWINE (HFD-645) 301-827-5849 , Team Leader

Overall Recommendation:

ACCEPTABLE on 14-DEC-1998 by J. D AMBROGIO (HFD-324) 301-827-0062
ACCEPTABLE on 12-MAY-1997 by M. EGAS (HFD-322) 301-594-0095

Establishment:

DMF No
AADA No:

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date 16-NOV-1998
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Establishment: 2027158
GENSIA INC
19 HUGHES
IRVINE, CA 926181902

DMF No:
AADA No:

Profile: SVS OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date 14-DEC-1998
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities: FINISHED DOSAGE MANUFACTURER

APPROVAL SUMMARY

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: **75-102** Date of Submission: **December 14, 1998**

Applicant's Name: **Gensia Laboratories, Ltd.**

Established Name: **Propofol Injectable Emulsion 1% (10 mg/mL)**

Approval Summary

Do you have 12 Final Printed Labels and Labeling? YES

1. CONTAINER - 20 mL, 50 mL, and 100 mL vials

   Satisfactory in FPL in the December 14, 1998 submission.

2. CARTON - 20 mL, 50 mL, and 100 mL

   Satisfactory in FPL in the December 14, 1998 submission.

3. INSERT

   Satisfactory in FPL in the December 14, 1998 submission.

Revisions Needed Post Approval But Prior To Marketing

see Commitment by firm dated 12/21/98

1. CONTAINER - 20 mL, 50 mL, and 100 mL vials

   a. Please add "Contains a Sulfite" with the **same prominence** as the total volume expression on the principal display panel and relocate to appear above the route of administration.

   b. Relocate "Rx only" to appear on the principal display panel.

2. CARTON - 20 mL, 50 mL, and 100 mL

   a. Relocate "Contains a Sulfite" to appear above the route of administration on the principal display panel.

   b. Relocate "Rx only" to appear on the principal display panel.

3. Transfer Label

Transfer labels are not reviewed by the Division however, we recommend that the phrase "Contains a Sulfite" be added to the label.

4. INSERT

a. The molecular weight of propofol should be 178.27 instead of 178.28 and chemically it should be described as 2,6-diisopropylphenol in the DESCRIPTION section.

b. Insert the word "injection" after the word "propofol" in the last sentence under Individualization of Dosage subsection of CLINICAL PHARMACOLOGY section.

c. Insert the word "classified" between the words "… recommended for children" and "ASA III or IV." in the fourth sentence, first paragraph, under Induction of General Anesthesia subsection of Pediatric Anesthesia subsection of CLINICAL PHARMACOLOGY section.

d. We note that you have included the statement "Contains sodium metabisulfite, a sulfite that…in non asthmatic people" in the PRECAUTIONS and DOSAGE AND ADMINISTRATION sections however, this statement should appear in WARNINGS section per 21 CFR 201.22(b).

e. Delete the last sentence, "Accidental clinical extravasation and intentional injection into subcutaneous or perivascular tissues of animals caused minimal tissue reaction." in the fifth paragraph under PRECAUTIONS section.

f. Please add "The syringe(s) should be labeled with appropriate information including the date and time the vial was opened." as the fifth sentence in the first paragraph under the Guidelines for Aseptic Technique for General Anesthesia/MAC Sedation subsection of the DOSAGE AND ADMINISTRATION section.

g. We encourage you to relocate "R_x *only*" to the TITLE section.

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Diprivan

NDA Number: 19-627

NDA DRUG Name:Diprivan

NDA Firm: Zeneca

Date of Approval of NDA Insert and supplement #: 6-11-96
Supplement - Formulation Revision (SCF-027) only in draft which could not be located by the last 3 labeling reviewers. The only labeling that could be obtained from the New Drug Division (ND) was the one Mr. David Kognistein personally found himself from the ND document room. The labeling, dated December 4, 1996, is not approved however, it is the only model labeling available and was used by previous labeling reviewers. Several requests have been made to get the approved RLD labels and labeling however we have not received any updated labeling nor seen any approved labeling supplements recently.

Has this been verified by the MIS system for the NDA? YES

Was this approval based upon an OGD labeling guidance? NO

Basis of Approval for the container labels: REGULATIONS

REVIEW OF PROFESSIONAL LABELING CHECKLIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?	X		
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book?	X		
If not USP, has the product name been proposed in the PI?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?		X	
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?		X	
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.	X		
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling (continued)	**Yes**	**No**	**N.A.**
Does OLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)	X		
Is the Manufactured by/Distributed statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	

Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?			X
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?			X
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.		X	
Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T ½ and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc or if none, please state.	X		

FOR THE RECORD

1. Gensia Laboratories originally submitted ANDA 75-102 for propofol injectable emulsion with 10 mg/mL prefilled syringe on March 31, 1997, as a result of several communications with OGD. The firm withdrew from this application the prefilled syringe with the and amended the application to provide for an alternate preservative system, 0.025% Sodium Metabisulfite, in vial sizes, 20 mL, 50 mL, and 100 mL.

2. MODEL LABELING - NDA 19-627 Diprivan® Injectable Emulsion 1%; Zeneca LTD: Approved 4-21-95 labeling issues, and 6-11-96 Supplement - Formulation Revision (SCF-027) approved labeling, revised 5-96.

3. This is a potential first generic.

4. INACTIVE INGREDIENTS - See page 100095 Section VIII, Volume 3.1. Note RLD cites Gensia cites "Glycerol" on the labels and labeling but Glycerin in the Components/Composition section. Glycerin USP monograph lists glycerol as an alternate name and this is acceptable. Also, Gensia chooses to refer to "Egg Lecithin" as "Egg yolk phospholipid". The chemist was consulted and finds this acceptable. It should be noted that the pH is now listed as 4.5 - 6.4 compared to 7 to 8.5. The pH difference was found to be acceptable by Dr. Mary Fanning.

5. PATENTS/EXCLUSIVITIES

Confirmed through Orange Book Cumulative Supplement 6 Jan'98-Jun'98.

Patent 4056635 expired 11-1-96.

Patent 4798846 expires on 3-19-97.

Patent 5714520 expires on March 22, 2015. Gensia states that this patent "will not be infringed upon by the manufacture, use, or sale by Gensia Sicor Pharmaceuticals, Inc., for which this amendment is submitted." Paragraph IV Certification cited.

Patent 5731355 provides for method of producing analgesia **expires March 22, 2015. Paragraph IV Certification cited.**

Patent 5731356 provides for a method for limiting the potential for microbial growth **expires March 22, 2015. Paragraph IV Certification cited.**

Exclusivities, I-99, for Pediatric Anesthesia in Children 3 years and older expired on 10-26-96.

Exclusivity, I-90, for Intensive Care Unit Sedation expired on 3-8-96.

Exclusivity, NP, for new product containing expires on June 11, 1999. According to the information listed in the 18TH edition of the Approved Drug Products, Zeneca Ltd., has been granted a period of marketing exclusivity for Diprivan®. The exclusivity granted will expire on June 11, 1999. Indication: New Product. Gensia states that they are "not seeking marketing approval for an preserved (Propofol) Injectable Emulsion, 10 mg/mL product."

6. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON
Not USP. Both ANDA and RLD: Store below 22°C (72°F). Do not store below 4°C (40°F). Refrigeration is not recommended.

The RLD storage recommendation has been revised to read "Store between 4° - 22°C (40° - 72°F). DO NOT FREEZE."

7. Gensia is the sole manufacturer of the drug product. See pp 335, 354 of original submission.

8. BIOEQUIVALENCE - Completed

9. PACKAGING CONFIGURATION
RLD: 20 mL ampuls, 50 mL and 100 mL infusion vials, and 20 mL and 50 mL pre-filled syringes.

ANDA: 20 mL single dose vials, and 50 mL and 100 mL infusion vials.

Earlier RLD labeling stated "Protect from light." However, newer labels do not have this statement. Also, in a previous review for another ANDA, the comment was made in the FTR that if packaged with nitrogen, the statement was not required.

10. The RLD has one revision in the box of warnings - "Supports rapid microbial growth" has been revised to read "Supports microbial growth". "Rapid" has been deleted. This does make sense based on the addition of retard growth. It is noted that this is not an antimicrobially preserved product under USP standards. To date, we have not received FPL for the 6-11/96 approved in draft for SCF labeling.

11. Gensia submitted an "IV Transfer Label". I have never seen such an approved label for the RLD. No comments will be made. We won't approve this. *This statement is from the previous review.*

12. BAIL BAND - A bail band will be attached to the bottom of each infusion vial.

13. TO FILTER OR NOT TO FILTER?

    See FTR dated 28-Apr-1997, from Laurence Landow, re: Innovator was told to delete the statement "Do not use in-line filters with this product". It was also noted on a memo dated 28-Feb-1997 that the Division was to send a letter to the innovator to delete the reference to the use of filters in the insert. Labels and labeling will be consistent to advise against the use of filters.

Date of Review: December 16, 1998 Dates of Submission: December 14, 1998

/S/

Primary Reviewer: Koung Lee

Team Leader: Charles V. Hoppes /S/ 12/21/98

cc:

12/21/98

RECORD OF TELEPHONE CONVERSATION

I contacted Tania Hoffman today as a follow-up to her conversation with Charlie Hoppes on 10/23/97.

She had questions regarding the review which was recently faxed to the firm.

After checking the jacket for ANDA 75-102, I was able to verify that the revision requested under CLINICAL PHARMACOLOGY: (Clinical Trials) ICU Sedation: (See WARNINGS...) Paragraph 6 - Revise the first sentence to read as follows: "In Medical Postsurgical ICU...". I confirmed that the "M" in Medical, and the "P" in Postsurgical must be capitalized.

I also confirmed the paragraph location for these corrections as paragraph 6.

DATE
10/24/97

ANDA NUMBER
75-102
74-816

IND NUMBER

TELECON

INITIATED BY APPLICANT/ SPONSOR: X
MADE BY TELE.: X
X FDA
_ IN PERSON

PRODUCT NAME
Propofol Injectable Emulsion

FIRM NAME
Gensia Laboratories Inc.

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Tania Hoffman

TELEPHONE NUMBER
(714) 457-2848

SIGNATURE

X:\NEW\FIRMSAM\GENSIA\TELECONS\75102OCT.97

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: **75-102** Dates of Submission: March 31, 1997

Applicant's Name: **Gensia Laboratories, Ltd.**

Established Name: **Propofol Injectable Emulsion 1% (10 mg/mL)**

Labeling Deficiencies:

1. CONTAINER - 20 mL Single Dose Syringe

   a. Please ensure the statement "SHAKE WELL BEFORE USE" appears prominently.

   b. Revise the statement "In addition to... adjust pH" to read:

      "Each mL contains...".

   c. Revise the storage recommendation statement to read:

      ... (40°-72°F). Do Not Freeze. Discard ...

   d. Per the USP monograph titles, use "Edetate Disodium" rather than "Disodium Edetate" and "Edetate Calcium Disodium" rather than "Calcium Disodium Edetate."

2. CARTON - 20 mL Single Dose Syringe

   See comments under CONTAINER.

3. INSERT

   a. GENERAL COMMENTS

      i. We note that your ANDAs 75-102 and 74-816 share a common insert. Please note that if your applications are not approved at the same time you may be asked to change your insert labeling accordingly. Also, the following comments refer to the insert submitted on June 27, 1997, for ANDA 74-816.

      ii. Throughout the text of the insert do not

capitalize "propofol" unless required to do so by sentence structure.

b. CLINICAL PHARMACOLOGY:

Clinical Trials

ICU Sedation: (See WARNINGS...)
Paragraph 2 - Revise the first sentence to read as follows:

"In Medical Postsurgical ICU..."

c. PRECAUTIONS

i. **Intensive Care Unit Sedation: (See WARNINGS...)**

Paragraph 8, line 1 - "Edetate Calcium Disodium" rather than "Calcium Edetate Disodium".

ii. Paragraph 5 - Revise the last sentence as follows:

...days following induction. Accidental clinical extravasation and intentional injection into subcutaneous or perivascular tissues of animals caused minimal tissue reaction. Intra-arterial...

d. DOSAGE AND ADMINISTRATION (Administration with Other Fluids:)

i. Fifth paragraph, line 10 - **SEDATION (SEE CLINICAL PHARMACOLOGY, Clinical Trials...**

ii. Please revise the following strength of the Large Volume Parenterals to appear as follows:

Dextrose Injection 5%
Lactated Ringers and Dextrose (5%)
Dextrose (5%) and Sodium Chloride (0.45%) Injection
Dextrose (5%) and Sodium Chloride (0.2%) Injection

Please revise your labels and labeling, as instructed above, and submit final printed container labels and carton labeling, and final print (or draft, if you prefer) insert labeling.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

RECORD OF TELEPHONE CONVERSATION

The project manager for these applications wanted us to make clear to the firm that the two applications can not be approved separately in this insert labeling since there is a shared insert.

I called Mr. Harrigan today to let him know this and to tell him that he can expect labeling comments soon for these applications.

DATE
10/21/97

ANDA NUMBER
74-816
75-102

IND NUMBER

TELECON

INITIATED BY APPLICANT/ SPONSOR X
MADE BY TELE.

X FDA _
IN PERSON

PRODUCT NAME
Propofol Injectable Emulsion 1%

FIRM NAME
Gensia Laboratories, LTD

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Donald Harrigan

TELEPHONE NUMBER
(714)455-4700

SIGNATURE
/S/

E L E C T R O N I C M A I L M E S S A G E

Date: 22-Oct-1997 07:46am EDT
From: Mark Anderson
ANDERSONM
Dept: HFD-617 MPN2 E210
Tel No: 301-827-5848 FAX 301-443-3839

TO: Ramakant Mhatre (MHATRE)

CC:
CC:

Subject: Status of Bio Waiver for Gensia Propofol

Ram,

I see from bar code locator that you have (had?) the B1.1 volume and Moo's waiver review of 75-102 (Gensia Propofol in syringes). We have a chemistry package ready to FAX.

I there any reason to expect the waiver will be denied?

I see that we have granted a waiver to a sister application from Gensia for a vial application 74-816 (also reviewed by Moo).

Thanks,

Mark

CDER Establishment Evaluation Report
for October 09, 1997

Application: ANDA 75102/000
Stamp: 01-APR-1997 Regulatory Due:
Applicant: GENSIA LABS
19 HUGHES
IRVINE, CA 927181902

Priority: Org Code: 600
Action Goal: District Goal: 01-JUN-1998
Brand Name:
Established Name: PROPOFOL
Generic Name:
Dosage Form: INJ (INJECTION)
Strength: 10MG/ML

FDA Contacts: K. SHERROD (HFD-617) 301-827-5849 , Project Manager
B. ARNWINE (HFD-645) 301-827-5849 , Team Leader

Overall Recommendation:

ACCEPTABLE on 12-MAY-1997 by M. EGAS (HFD-322) 301-594-0095

Establishment:

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDAT 05-MAY-1997
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Establishment: 2027158
GENSIA INC
19 HUGHES
IRVINE, CA 927181902

DMF No:

AADA No:

Profile: SVS OAI Status: NONE
Last Milestone: OC RECOMMENDAT 12-MAY-1997
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities: FINISHED DOSAGE MANUFACTURER

Application: ANDA 75102/000
Stamp: 01-APR-1997 Regulatory Due:
Applicant: GENSIA LABS
19 HUGHES
IRVINE, CA 927181902

Priority: Org Code: 600
Action Goal: District Goal:
Brand Name:
Established Name: PROPOFOL
Generic Name:
Dosage Form: INJ (INJECTION)
Strength: 10MG/ML

FDA Contacts: K. SHERROD (HFD-617) 301-594-1300 , Project Manager
B. ARNWINE (HFD-645) 301-594-1300 , Team Leader

Overall Recommendation:

Establishment

Responsibilities:
DRUG SUBSTANCE MANUFACTURER

Establishment: 2027158
GENSIA INC
19 HUGHES
IRVINE, CA 927181902

DMF No:

Responsibilities:
FINISHED DOSAGE MANUFACTURER

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: **75-102** Dates of Submission: March 31, 1997

Applicant's Name: **Gensia Laboratories, Ltd.**

Established Name: **Propofol Injectable Emulsion 1% (10 mg/mL)**

Labeling Deficiencies:

1. CONTAINER - 20 mL Single Dose Syringe

   a. Please ensure the statement "SHAKE WELL BEFORE USE" appears prominently.

   b. Revise the statement "In addition to... adjust pH" to read:

      "Each mL contains...".

   c. Revise the storage recommendation statement to read:

      ... (40°-72°F). Do Not Freeze. Discard ...

   d. Per the USP monograph titles, use "Edetate Disodium" rather than "Disodium Edetate" and "Edetate Calcium Disodium" rather than "Calcium Disodium Edetate."

2. CARTON - 20 mL Single Dose Syringe

   See comments under CONTAINER.

3. INSERT

   a. GENERAL COMMENTS

      i. We note that your ANDAs 75-102 and 74-816 share a common insert. Please note that if your applications are not approved at the same time you may be asked to change your insert labeling accordingly. Also, the following comments refer to the insert submitted on June 27, 1997, for ANDA 74-816.

      ii. Throughout the text of the insert do not

capitalize "propofol" unless required to do so by sentence structure.

b. CLINICAL PHARMACOLOGY:

Clinical Trials

ICU Sedation: (See WARNINGS...)
Paragraph 2 - Revise the first sentence to read as follows:

"In Medical Postsurgical ICU..."

c. PRECAUTIONS

i. **Intensive Care Unit Sedation: (See WARNINGS...)**

Paragraph 8, line 1 - "Edetate Calcium Disodium" rather than "Calcium Edetate Disodium".

ii. Paragraph 5 - Revise the last sentence as follows:

...days following induction. Accidental clinical extravasation and intentional injection into subcutaneous or perivascular tissues of animals caused minimal tissue reaction. Intra-arterial...

d. DOSAGE AND ADMINISTRATION (Administration with Other Fluids:)

i. Fifth paragraph, line 10 - **SEDATION (SEE CLINICAL PHARMACOLOGY, Clinical Trials...**

ii. Please revise the following strength of the Large Volume Parenterals to appear as follows:

Dextrose Injection 5%
Lactated Ringers and Dextrose (5%)
Dextrose (5%) and Sodium Chloride (0.45%) Injection
Dextrose (5%) and Sodium Chloride (0.2%) Injection

Please revise your labels and labeling, as instructed above, and submit final printed container labels and carton labeling, and final print (or draft, if you prefer) insert labeling.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW OF PROFESSIONAL LABELING CHECKLIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?	X		
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23		X	
Is this name different than that used in the Orange Book?	X		
If not USP, has the product name been proposed in the PF?		X	
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?		X	
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?		X	
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.	X		
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominance? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	

Labeling (continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)	X		
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?			X
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?		X	
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?			X
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)			X
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?			X
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.		X	

Bioequivalence Issues: (Compare bioequivalency values: insert to study. List Cmax, Tmax, T ½ and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.	X		

FOR THE RECORD: (portions brought forward from last review.)

1. MAJOR ISSUES - Gensia originally filed this ANDA with a non containing formulation. They received an NA letter dated 8-8-96 based on the original submission. They amended on 9-18-96. However, subsequently, they reformulated to add and amended again on 12-24-96. With this amendment, they withdrew the non- formulation for consideration. Thus, this review is of the container labels and carton and insert labeling of the new containing product.

2. MODEL LABELING - Diprivan® Injectable Emulsion 1%; Zeneca LTD: Approved 4-21-95 labeling issues, and 6-11-96 Supplement - Formulation Revision (SCF) approved labeling, revised 5-96.

3. This is a potential first generic.

4. INACTIVE INGREDIENTS - See page 100105 Section VII Volume 4.1. Note RLD cites "glycerin". Gensia cites "Glycerol" on labels, labeling. Glycerin USP monograph lists glycerol as an alternate name and this is acceptable. Also, Gensia chooses to refer to "Egg Lecithin" as "Egg yolk phospholipid". The chemist was consulted and finds this acceptable.

5. PATENTS/EXCLUSIVITIES - Confirmed through O Book Cumulative Supplement 6 Jan'97-Jun'97.
Two patents: Patent 4056635 expired 11-1-96. Patent 4798846 expires on 3-19-97.
Both exclusivities are now expired: I-99, for Pediatric Anesthesia in Children 3 years and older on 10-26-96. Exclusivity, I-90, for Intensive Care Unit Sedation expired on 3-8-96. Gensia certified incorrectly that both patents expired 11-1-96.

According to the information listed in the 17th edition of the Approved Drug Products, Zeneca Ltd., has been granted a period of marketing exclusivity for Diprivan®. The exclusivity granted will expire on June 11, 1999. Indication: New Product. Gensia does not intend to market this product prior to the expiration date of June 11, 1999.

6. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON
Not USP. Both ANDA and RLD: Store below 22°C (72°F). Do not store below 4°C (40°F). Refrigeration is not recommended.
The RLD storage recommendation has been revised to read "Store between 4° - 22°C (40° - 72°F). DO NOT FREEZE."

7. Gensia is the sole manufacturer of the drug product. See pp 335, 354 of original submission. ANDA has same manufacturing process as companion ANDA ~~75-102~~ 74-816 (vials).

8. BIOEQUIVALENCE - Pending. New waiver requested. See section VI of volume 4.1.

8. PACKAGING CONFIGURATION
RLD: 20 mL ampuls, 50 mL and 100 mL infusion vials, and 20 mL and 50 mL pre-filled syringes.

ANDA: 20 mL single dose vials, and 50 mL and 100 mL infusion vials, and 20 mL pre-filled syringes.

Earlier RLD labeling stated "Protect from light." However, newer labels do not have this statement. Also, in a previous review for another ANDA, the comment was made in the FTR that if packaged with nitrogen, the statement was not required.

10. The firm is asked to use rather than n their labels and labeling to be consistent with the USP 23 monograph title. Likewise, rather than

The RLD has one revision in the box of warnings - "Supports rapid microbial growth" has been revised to read "Supports microbial growth". "Rapid" has been deleted. This does make sense based on the addition of m to retard growth. It is noted that this is not an antimicrobially preserved product under USP standards. To date, we have not received FPL for the 6-11/96 approved in draft for SCF labeling.

11. Gensia submitted an "IV Transfer Label". See p. 100072. I have never seen such an approved label for the RLD. No comments will be made. We won't approve this.

12. BAIL BAND - We previously commented for the infusion vials that there is no indication that a plastic bail band or some other means is present to hang these vials for infusion. The firm replied in its 9-18-96 amendment (p. 10) that a bail band will be attached to the bottom of each infusion vial.

13. TO FILTER OR NOT TO FILTER?

    See FTR dated 28-Apr-1997, from Laurence Landow, re: Innovator being told to delete the statement "Do not use in-line filters with this product". It was also noted on a memo dated 28-Feb-1997 that the Division was to have sent a letter to the innovator to delete reference to the use of filters in the insert. Labels and labeling will be consistent to advise against the use of filters.

Date of Review: 10/20/ 1997 Dates of Submission: 3/31/1997

/S/ 10/20/97

Primary Reviewer: Julia Johnson Date: 10/20/97

Team Leader: Charles V. Hoppes Date:

/S/ 10/21/97

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001
Expiration Date: April 30, 1994
See OMB Statement on Page 3.

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314).*

NAME OF APPLICANT	DATE OF SUBMISSION
Gensia Laboratories, Ltd.	3/31/97
ADDRESS *(Number, Street, City, State and Zip Code)* 19 Hughes Irvine, CA 92616	TELEPHONE NUMBER *(Include Area Code)* (714) 457-4709
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER *(If previously issued)* ANDA No. To be Assigned

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(If any)*
Propofol Injectable Emulsion	Diprivan®

CODE NAME *(If any)*	CHEMICAL NAME
–	2,6 - diisopropylphenol

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
Emulsion	Intravenous	10 mg/mL

PROPOSED INDICATIONS FOR USE
Propofol Injectable Emulsion is indicated for both induction and/or maintenance of anesthesia as part of a balanced anesthetic technique for inpatient and outpatient surgery.

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:
74-816

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check One)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☒ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) *(21 CFR 314.55)*

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION
Diprivan®	Zeneca, Ltd.

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☐ AN AMENDMENT TO A PENDING APPLICATION. ☐ SUPPLEMENTAL APPLICATION
☒ ORIGINAL APPLICATION ☐ RESUBMISSION

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APR 1 1997
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SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g. Part 314.70 (B)(2)(iv)) Part 314.92

PROPOSED MARKETING STATUS *(Check one)*

☒ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

100001

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APP1032

CONTENTS OF APPLICATION

This application contains the following items: *(Check all that apply)*

X	1. Index
X	2. Summary *(21 CFR 314.50 (c))*
X	3. Chemistry, manufacturing, and control section *(21 CFR 314.50 (d) (1))*
	4. a. Samples *(21 CFR 314.50 (e) (1))* (Submit only upon FDA's request)
X	b. Methods Validation Package *(21 CFR 314.50 (e) (2) (i))*
	c. Labeling *(21 CFR 314.50 (e) (2) (ii))*
X	i. draft labeling *(4 copies)*
	ii. final printed labeling *(12 copies)*
	5. Nonclinical pharmacology and toxicology section *(21 CFR 314.50 (d) (2))*
	6. Human pharmacokinetics and bioavailability section *(21 CFR 314.50 (d) (3))*
	7. Microbiology section *(21 CFR 314.50 (d) (4))*
	8. Clinical data section *(21 CFR 314.50 (d) (5))*
	9. Safety update report *(21 CFR 314.50 (d) (5) (vi) (b))*
	10. Statistical section *(21 CFR 314.50 (d) (6))*
	11. Case report tabulations *(21 CFR 314.50 (f) (1))*
	12. Case reports forms *(21 CFR 314.50 (f) (1))*
X	13. Patent information on any patent which claims the drug *(21 U.S.C. 355 (b) or (c))*
X	14. A patent certification with respect to any patent which claims the drug *(21 U.S.C. 355 (b) (2) or (j) (2) (A))*
	15. OTHER *(Specify)*

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warning, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

1. **Good manufacturing practice regulations in 21 CFR 210 and 211.**
2. **Labeling regulations in 21 CFR 201.**
3. **In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.**
4. **Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.**
5. **Regulations on reports in 21 CFR 314.80 and 314.81.**
6. **Local, State and Federal environmental impact laws.**

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
Donald J. Harrigan, R.Ph. **Director, Regulatory Affairs**	Donald J. Harrigan	3/31/97

ADDRESS *(Street, City, State, Zip Code)*	TELEPHONE NO. *(Include Area Code)*
19 Hughes, Irvine, CA 92618	**(714) 457-4709**

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

100002

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APP1033

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-102

CORRESPONDENCE

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

December 28, 1998

NEW CORRESP
NC to Fax

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

TELEPHONE AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite. Reference is also made to the telephone conversation between Mr. Raymond Brown of the Agency and myself on December 28, 1998, in which Mr. Brown requested that Gensia Sicor reinstitute the Free Fatty Acid test and specification (NMT meq/mL) for the finished product.

Therefore, in accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, Gensia Sicor Pharmaceuticals, Inc., hereby amends this application and commits to incorporating the Free Fatty Acid test and specification for the finished product as specified by the Agency. We further commit to assuring that the addition requested by FDA will be reflected in the quality control and stability documentation prior to the commercial launch of this product. This documentation will be provided as a post-approval supplement.

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO75102\AMENDS\AMEND15.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

GensiaSicor™
PHARMACEUTICALS

December 21, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N/A F

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

TELEPHONE AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite. Reference is also made to the Agency's facsimile dated December 21, 1998.

Therefore, in accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, Gensia Sicor Pharmaceuticals, Inc., hereby amends this application and commits to incorporate the labeling revisions specified in the Agency's facsimile dated December 21, 1998. We further commit to assuring that the revisions requested by FDA will be reflected in the labeling utilized for the commercial launch of this product.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO7510Z\AMENDS\AMEND14.WPD
cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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Gensia Sicor Pharmaceuticals, Inc. • 19 Hughes • Irvine CA • 92618-1902 • USA
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083

GensiaSicor™
PHARMACEUTICALS

NDA DRUG AMENDMENT
AC

December 28, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

TELEPHONE AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite. Reference is also made to the telephone conversation between Mr. Raymond Brown of the Agency and myself on December 28, 1998, in which Mr. Brown requested that Gensia Sicor reinstitute the Free Fatty Acid test and specification (NMT neq/mL) for the finished product.

Therefore, in accordance with the provisions of Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, Gensia Sicor Pharmaceuticals, Inc., hereby amends this application and commits to incorporating the Free Fatty Acid test and specification for the finished product as specified by the Agency. We further commit to assuring that the addition requested by FDA will be reflected in the quality control and stability documentation prior to the commercial launch of this product. This documentation will be provided as a post-approval supplement.

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Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PDOD7512\AMENDS\AMEND15.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

GensiaSicor™
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December 15, 1998

NEW NUMBER?
N/C

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite in the formulation, ANDA 75-102, submitted January 16, 1998.

In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21*, we hereby amend our application to update the exclusivity statement.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain K. Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

RECEIVED
DEC 16 1998
GENERIC DRUGS

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

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December 14, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

NDA [illegible] AMENT
N/A F

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite in the formulation, ANDA 75-102, submitted January 16, 1998. Reference is also made to the Agency's facsimile dated December 11, 1998.

In accordance with the provisions of Section 314.96 of the *Code of Federal Regulations, Title 21*, we hereby amend our application to provide the change in labeling as requested.

Please note that a number of changes to the package insert requested by the Agency were not required. Specifically, we did not incorporate the deletion of the text in the insert as identified in sections b. and c.(ii). After careful review of our labeling, we determined that this text does not appear in the last revision of our package insert for the propofol vial products.

Furthermore, we did not add the text to the insert as identified in section c.(iii). Upon review of our previous revision of the package insert, we determined that this text had already been incorporated.

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DEC 15 1998
GENERIC [illegible]

Gensia Sicor Pharmaceuticals, Inc. • 19 Hughes • Irvine CA • 92618-1902 • USA
Phone (949) 455-4700, (800) 729-9991 • Fax (949) 855-8210 • http://www.gensiasicor.com

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APP1041

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or Mr. Dwain K. Allen at (949) 457-2861. We may also be contacted by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

S:\PRO75102\AMENDS\AMEND12.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

November 10, 1998

Desk Copy
for
Mr. Peter Rickman

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion 1%
Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

At this time we wish to notify the Agency of the legal actions taken by Zeneca Ltd. against Gensia Sicor regarding the Paragraph IV Patent Certification for Gensia Sicor's Propofol Injectable Emulsion 1% containing 0.025% Sodium Metabisulfite (ANDA 75-102).

In accordance with the provisions of Section 314.107(f)(2) of the *Code of Federal Regulations, Title 21*, we hereby amend our application to inform the Agency of the legal actions taken by Zeneca Ltd. On April 3, 1998, Zeneca Ltd. initiated a patent infringement suit (patent 5,714,520) against Gensia Sicor in the United States District Court for the District of Delaware (Zeneca Limited v. Gensia Sicor Pharmaceuticals, Inc., Civil Action No. 98-170). On April 17, 1998, Zeneca dismissed the law suit. A copy of the initial action and the subsequent dismissal are provided in **Attachment 1** and **Attachment 2**, respectively.

Gensia Sicor Pharmaceuticals, Inc. • 19 Hughes • Irvine CA • 92618-1902 • USA
Phone (949) 455-4700, (800) 729-9991 • Fax (949) 855-8210 • http://www.gensiasicor.com

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (949) 457-2808 or by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

Attachments

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

Gensia Sicor™
PHARMACEUTICALS

August 24, 1998

VIA FACSIMILE AND FEDERAL EXPRESS

Mr. Gordon Johnston
Office of Generic Drugs
Center for Drug Evaluation & Research
Food and Drug Administration
Metro Park North II, HFD-600
7500 Standish Place
Rockville, MD 20855-2773

Confidential Communication
Contains Proprietary Information
Exempt from Disclosure under
the Freedom of Information Act

RE: Propofol Injectable Emulsion
Alternative Preservative System
ANDA 75-102

Dear Mr. Johnston:

Reference is made to Gensia Sicor's correspondence dated July 17, 1997, in which we requested the FDA's evaluation of an alternate Propofol formulation utilizing sodium metabisulfite as the preservative agent. Reference is also made to our response to the Agency dated June 15, 1998, regarding the adult exposure levels of sulfites expected under the ICU indication, when a patient receives the proposed formulation of Propofol Injectable Emulsion in combination with total parenteral nutrition (TPN) products that also contain sulfites. Further reference is made to the recent telephone conference on August 19, 1998, between Gensia Sicor and the Office of Generic Drugs to discuss additional information relative to the safety of sodium metabisulfite as a preservative in our proposed product.

As a result of the telephone conference, we wish to provide additional information to support the safety of sodium metabisulfite as a preservative in our proposed formulation of Propofol Injectable Emulsion. Specifically, we wish to address the following issues that were raised during this conference:

1) The potential for sulfite hypersensitivity reactions occurring from the sodium metabisulfite contained in our formulation of Propofol.

2) Pediatric dose exposure levels of sulfites expected for the proposed formulation of Propofol as indicated in anesthesia maintenance when compared to sulfite-containing TPN products.

3) Pediatric dose exposure levels of sulfites expected for the proposed formulation of Propofol as indicated in anesthesia induction when

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Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

compared to other sulfite-containing injectable products.

4) A comparison of adult and elderly dose exposure levels of sulfites expected from more immediate administration (i.e., dose administered within 1 minute) of the proposed formulation of Propofol and other sulfite-preserved injectable products.

5) A comparison of risk between the preserving agents that is used in Zeneca's Diprivan (propofol) Injectable Emulsion, and sodium metabisulfite, that is used in Gensia Sicor's formulation of Propofol Injectable Emulsion.

Sulfite Hypersensitivity

Sulfite hypersensitivity is an adverse reaction associated with food and drug products preserved with sulfite agents. In the 1970's and 1980's, FDA received several case reports of adverse reactions to sulfite additives from foods and drugs. The reported adverse reactions included wheezing, bronchospasm, dyspnea, stomach cramps, flushing, hypotension, urticaria, and anaphylaxis.[1] In 1986, Celeste reported that FDA was aware of approximately 500 reports of adverse reactions to sulfites in foods, including 12 fatal cases allegedly involving sulfites. Adverse reactions to drugs containing sulfites were also reported. FDA noted that the adverse reactions appeared to be relegated to a sub-population of asthmatics; and to a rare number in the non-asthmatic population. In response to the reports of hypersensitivity reactions associated with sulfites, FDA took three separate regulatory actions. In August 1986, FDA promulgated a regulation to ban the use of sulfites in fresh fruits and vegetables.[2] In another regulation, the Agency required packaged foods containing sulfites to be labeled if sulfites are present at levels equal to or greater than 10 ppm.[3] The third regulatory action in June 1987 was to amend the drug labeling regulations to require a

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[1] Celeste, A. Update on Sulfites. *Assoc. Food Drug U.S. Off. Q. Bull.* 50:46, 1986. (As reported in Gunnison, A.F. & Jacobsen, D.W. Sulfite Hypersensitivity: A Critical Review. *CRC Critical Reviews in Toxicology*. 17 (3):185-214, 1987.)

[2] Sulfiting agents: revocation of GRAS status for use on fruits and vegetables intended to be served or sold raw to consumers. *Federal Register*, 51 (131):25021-25026, July 9, 1986.

[3] Food labeling: declaration of sulfiting agents. *Federal Register*, 51 (131):25012-250206, July 9, 1986.

sulfite warning in the package insert of drug products containing sulfite preservatives.[4] The Agency's actions were taken to safeguard, in particular, the hypersensitive asthmatic sub-population.

According to Gunnison and Jacobsen, approximately 5-10% of all asthmatics are sulfite hypersensitive.[5] Of the nearly 14.6 million Americans with asthma as estimated in 1994,[6] this translates to a sub-population of 0.73 - 1.46 million asthmatics who are possibly reactive to sulfites and, in general, represents 0.3 - 0.6% of the U.S. population.[7] According to Gunnison and Jacobsen, chronic asthma is the predominant predisposing factor that leads to sulfite hypersensitivity.[5]

It is suggested that sulfite oxidase deficiency in chronic asthmatics may play a role in the sulfite hypersensitivity. Specifically, chronic asthmatics with sulfite oxidase deficiency may be unable to adequately metabolize exogenous sulfites. However, the mechanism by which systemic sulfites trigger a hypersensitivity reaction is not yet know. From the review of several studies involving provocative challenge protocols and case reports of individual patients as summarized by Gunnison and Jacobsen, the hypersensitivity reaction to sulfites does not appear to be dose-related, but represents an idiosyncratic response.[5] Variations in the dose and route of administration appear to elicit varying degrees of reaction in different individuals.

In general, exogenous sulfites are rapidly oxidized to sulfate via sulfite oxidase and secreted in the urine as sulfate. The capacity of sulfite oxidase for sulfite oxidation is extremely high compared with the normal sulfite load from exogenous and endogenous sources. Because of its rapid metabolic clearance, sulfite does not accumulate in the tissues. Usually, no free sulfite is detected in plasma. Free sulfite has been reported in the plasma of a child diagnosed as deficient in sulfite oxidase.[8]

Furthermore, sedation does not affect the elimination of sulfite. This is supported by the similar sulfite clearance in a rhesus monkey while sedated as compared to normal

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[4] Sulfiting agents: labeling in drugs for human use, warning statement. *Federal Register*, 51 (234):43900-43904, December 5, 1986.

[5] Gunnison, A.F. & Jacobsen, D.W. Sulfite Hypersensitivity: A Critical Review. *CRC Critical Reviews in Toxicology*. 17 (3):185-214, 1987.

[6] *Vital and Health Statistics*. Series 10, No. 193

[7] Based upon U.S. population of 265.3 million in 1996 by the U.S. Census Bureau.

[8] Gunnison, A. F. Sulphite Toxicity: A Critical Review of In-Vitro and In-Vivo Data. *Food and Cosmetic Toxicology*. 19: 667-682, 1981.

experimental conditions.[9] Therefore, we believe that Propofol Injectable Emulsion with sodium metabisulfite will be well tolerated over an extended period, and also the clearance of sodium metabisulfite will not be affected by the action of Propofol.

In relation to the sodium metabisulfite added to our formulation of Propofol Injectable Emulsion, Gensia Sicor recognizes the potential risk of sulfite hypersensitivity reactions by this sub-population of asthmatics, and in rare cases, a sub-population of non-asthmatics. We believe this risk is mitigated by the application of the FDA-required warning statement for sulfites on the drug labeling. The warning is intended to alert health care practitioners of the risk to patients with *known* hypersensitivity to sulfites.

In the event the hypersensitivity is not disclosed in the course of the patient's history, and a reaction is manifested following the administration of Gensia Sicor's Propofol product, the patient will present with the reaction in a hospital setting, pursuant to the indications, to allow immediate medical measures to be taken. The key indices of the sensitivity reaction are wheezing and bronchospasm in the asthmatic. Both reactions are readily identifiable by the clinician (even when the patient is under anesthesia) such that treatment can be initiated immediately.

Propofol Pediatric Dose for Maintenance of General Anesthesia - Exposure Levels of Sulfites from Propofol Compared to TPN Products

To determine pediatric dose exposure levels of sulfites resulting from the administration of Gensia Sicor's formulation of Propofol as indicated in anesthesia maintenance and compared to sulfite-containing TPN products, we have performed an evaluation for pediatric patients assuming standard weights for a newborn (3.5 kg), an infant (12 kg), and a child (30 kg). It should be noted that **Propofol is not recommended for administration to children less than 3 years old nor is the product recommended for ICU or MAC sedation in children, in general. Propofol is only indicated for general anesthesia in children age 3 years and older.** Although the sulfite exposure due to TPN products in children (≥ 3 years) is of most interest for the purposes of direct comparison to sulfite doses resulting from administration of Propofol, information regarding the sulfite exposure levels from TPN products in newborns and infants are also presented as a point of interest.

For a pediatric patient 3 years of age or older undergoing maintenance of general anesthesia, the theoretical levels of sulfite exposure expected from the administration of Gensia Sicor's sodium metabisulfite formulation of Propofol is expected to be 13.5 mg/hr. We arrived at a theoretical hourly amount of sodium metabisulfite based upon a maintenance dose for general anesthesia of 18 mg/kg/hr of Propofol, assuming a standard weight pediatric patient of 30 kg, i.e.,

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[9] Gunnison et al. Comparative Sulfite Metabolism in the Rat, Rabbit, and Rhesus Monkey. *Toxicology and Applied Pharmacology*. 42: 99-109, 1977.

(18 mg/kg/hr) X (30 kg) X [(0.25 mg/mL SMBS)/(10 mg/mL Propofol)]

= 13.5 mg SMBS/hr.

Table 1 summarizes information from *Facts and Comparison* (1997),[10] which lists the amounts of sulfite preservatives contained in various amino acid solutions and the relation to pediatric product doses in newborns, infants, and children. The dosage information for each TPN product is based upon the *pediatric* TPN protocols described in *Facts and Comparison* (1997).[10] This table further summarizes the amount of sulfite exposure expected.

Table 1

Product	Preservative	Preservative Dose (mg/hr)*		
		Newborn (3.5 kg)	Infant (12 kg)	Child (30 kg)
Aminosyn II 5% (Abbott)	20 mg/dL Sodium Hydrosulfite	2.2	7.5	19
Aminosyn II 10% (Abbott)	20 mg/dL Sodium Hydrosulfite	1.1	3.8	9.4
Aminosyn-PF 10% (Abbott)	230 mg/100 mL Sodium Hydrosulfite	13	43	108
Aminosyn 15% (Abbott)	60 mg/100 mL Sodium Hydrosulfite	2.2	7.5	19
TrophAmine 6% (McGaw)	< 50 mg/100 mL Sodium Metabisulfite	4.6	16	39
TrophAmine 10% (McGaw)	< 50 mg/100 mL Sodium Metabisulfite	2.7	9.4	23
FreeAmine III 8.5% (McGaw)	<0.1 g/100 mL Sodium Bisulfite	6.4	22	55
FreeAmine III 10% (McGaw)	<0.1 g/100 mL Sodium Bisulfite	5.5	19	47
Novamine 15% (Abbott)	30 mg/100 mL Sodium Bisulfite	1.1	3.8	9.4
Aminosyn-RF 5.2% (Abbott)	60 mg/100 mL Sodium Metabisulfite	6.3	22	54
NephrAmine 5.4% (McGaw)	< 0.05 g/100 mL Sodium Bisulfite	5.1	17	43
HepatAmine 8% (McGaw)	< 100 mg/100 mL Sodium Bisulfite	NP**	NP	59

* TPN Pediatric Protocol: 150 mL/kg/day of a 2.5% Amino Acid solution (equivalent to 3.75 g/kg/day)
** NP = Not Provided

[10] For the specific list of page references for each drug product discussed, refer to **Attachment 1.**

For children 3 years of age or older, TPN solutions were determined to yield sulfite preservative doses (up to 108 mg/hr), in general, greater than or equivalent to the theoretical level of exposure (13.5 mg/hr) from Propofol containing sodium metabisulfite, when administered for pediatric anesthesia maintenance. Additionally, the sulfite exposure for newborns (up to 13 mg/hr) and infants (up to 43 mg/hr) when receiving TPN products are also in the range of the 13.5 mg/hr exposure experienced by a pediatric patient (≥ 3 years) receiving Gensia Sicor's formulation of Propofol. It is important to note that Aminosyn-PF 10% is marketed specifically for pediatric administration and, in this evaluation, represents the highest dose of sulfite (108 mg/hr) to the pediatric patient 3 years of age and older in comparison to other TPN products.

In certain clinically compromised states, TPN products containing sulfites are indicated for pediatric administration. Specifically, Aminosyn-RF 5.2% and NephrAmine 5.4% are indicated for treatment of renal failure; and HepatAmine is specially formulated for the treatment of hepatic failure/hepatic encephalopathy. Pediatric patients (≥ 3 years) receiving these TPN solutions are exposed to sulfites of 43 to 54 mg/hr, which is in excess of the expected sulfite exposure of 13.5 mg/hr when our proposed formulation of Propofol is administered. Based upon the pediatric dose contributed from approved TPN products in the most compromised patients, it is expected that the levels of sulfite from Gensia Sicor's formulation of Propofol should be well tolerated in both health and compromised patients.

In conclusion, the total contribution of sulfite from amino acid TPN products for pediatric indications correlates to levels of sulfite expected to be safe for administration of Gensia's Propofol Injectable Emulsion for pediatric maintenance anesthesia.

Propofol Pediatric Dose for Induction of General Anesthesia - Exposure Levels of Sulfites from Propofol Compared to Other IV Products

For a comparison of immediate administration (i.e., dose administered within 1 minute), theoretical levels of sulfite exposure expected for pediatric patients receiving parenteral products containing sulfites were compared to sulfite levels expected to be contributed by Gensia Sicor's formulation of Propofol based upon the pediatric dosing for induction of general anesthesia. For purposes of this analysis, pediatric dosing will focus upon children 3 years or older, however, information for newborns and infants is also of interest. The evaluation includes the overall scope of sulfite exposure to pediatric patients from two approved drug products, Gallamine Triethiodide (20 mg/mL) and Tubocurarine Chloride (3 mg/mL). As in the previous section, the assumption for pediatric standard weights remains the same. Since Propofol is not recommended for administration to children less than 3 years old, comparison to short term exposure to sulfites in children 3 years of age or older is of greatest value.

For a pediatric patient 3 years of age or older, the theoretical levels of sulfite exposure expected from the administration of the Gensia Sicor's sodium metabisulfite formulation of Propofol for induction of general anesthesia (i.e., per labeling, 2.5 - 3.5 mg/kg over

20 - 30 sec.) have been calculated. The theoretical amounts of sodium metabisulfite based upon dosing for induction were determined as follows:

Induction

(2.5 - 3.5 mg/kg) X (30 kg) X [(0.25 mg/mL SMBS)/(10 mg/mL Propofol)]

= 1.9 - 2.6 mg SMBS in 20 to 30 sec.

Review of *Facts and Comparison* (1997)[11] for other products containing sulfites which list pediatric dosing protocols provided two drugs used as adjuncts to anesthesia: Gallamine Triethiodide (20 mg/mL) and Tubocurarine Chloride (3 mg/mL). These two products compare well to Gensia Sicor's Propofol, because both contain the same sulfite preservative, sodium metabisulfite, and both are used in a surgical setting. The levels of sodium metabisulfite exposure from these products based upon the pediatric protocols are provided in **Table 2** below:

Table 2

Product	Preservative	Method of Administration	Preservative Dose (mg)		
			Newborn (3.5 kg)	Infant (12 kg)	Child (30 kg)
Gallamine Triethiodide, 20 mg/mL (Davis + Geck)	2.5 mg/mL Sodium Metabisulfite	*Initial: 1.5 mg/kg* *Repeat: 1 mg/kg after 30-40 min. as needed*			
		Initial Dose	0.66	2.3	5.6
		Repeat Dose	0.44	1.5	3.8
Tubocurarine Chloride, 3 mg/mL (Abbott)	1 mg/mL Sodium Metabisulfite	*Neonates: 0.3 mg/kg* *Children: 0.6 mg/kg* *Sustained injection in 1-1.5 min.*			
		Initial (1 min.)	0.35	2.4	6.0
		Repeat Dose	0.35	2.4	6.0

In pediatric protocols for immediate administration, the exposure level of sodium metabisulfite ranges from 3.8 to 6.0 mg for the two approved products, Gallamine Triethiodide and Tubocurarine Chloride. This range is comparable to the expected levels of sulfite from the dosing of Propofol with sodium metabisulfite during pediatric induction. Therefore, the sulfite exposure due to Propofol for pediatric induction would

[11] For the specific list of page references for each drug product discussed, refer to **Attachment 1.**

be expected to correlate with safe levels as supported by the two approved products.

Adult and Elderly Dose-Exposure Levels of Sulfites from Propofol Compared to Other IV Products

For a comparison of immediate administration in adult and elderly patients, theoretical levels of sulfite exposure expected for these groups receiving parenteral products containing sulfites were compared to sulfite levels expected from Gensia Sicor's formulation of Propofol. Comparisons were made based upon the recommended Propofol dosing for bolus injection, induction and maintenance for general anesthesia and MAC sedation. Information with regard to the dosing of the comparator products was obtained from *Facts and Comparison* (1997).

The levels of sulfite exposure from various injectable products as well as the sulfite exposure levels from Propofol were calculated for the adult and elderly indications. The theoretical amounts of sulfite for the Propofol and the comparator products are summarized in **Table 3** and **Table 4**, respectively.

Table 3

Product Description	Preservative Concentration	Method of Administration	Preservative Dose	
			Elderly (70 kg)	Adult (70 kg)
Propofol Injectable Emulsion, 1% (Gensia Sicor)	0.025% Sodium Metabisulfite	*General Anesthesia:* *Bolus injection - 50 mg per as required* *Elderly - 1.5 mg/kg for induction (10 sec)* *Maintenance @ 100 mcg/kg/min.* *Adult - 2.5 mg/kg for induction (10 sec)* *Maintenance @ 200 mcg/kg/min.*		
		Intermittent Bolus	12.5 mg	12.5 mg
		Induction	2.63 mg	4.38 mg
		Maintenance	10.5 mg/hr	21 mg/hr
		MAC Sedation: *Elderly - 0.5 mg/kg for induction (5 min)* *Maintenance @ 20% of 75 mcg/kg/min.* *Adult - 0.5 mg/kg for induction (5 min)* *Maintenance @ 75 mcg/kg/min.*		
		Induction	0.88 mg	0.88 mg
		Maintenance	6.3 mg/hr	7.9 mg/hr

Table 4

Product Description	Preservative Concentration	Method of Administration	Preservative Dose	
			Elderly (70 kg)	Adult (70 kg)
Gallamine Triethiodide, 20 mg/mL (Davis + Geck)	2.5 mg/mL Sodium Metabisulfite	*Adjunct to Anesthesia:* *Initial dose - Max of 100 mg* *Repeat dose - 1 mg/kg every 30-40 min as needed*		
		Initial Dose	12.5 mg	12.5 mg
		Repeat Dose	8.75 mg	8.75 mg
Tubocurarine Chloride, 3 mg/mL (Abbott)	1 mg/mL Sodium Metabisulfite	*Adjunct to Anesthesia:* *Initial dose - sustained injection of 0.6 mg/kg* *Repeat dose - 0.6 mg/kg every 30-40 min. as needed*		
		Initial (1 min.)	14 mg	14 mg
		Repeat Dose	14 mg	14 mg
Intropin (dopamine), 40 mg/mL (Faulding)	1% Sodium Metabisulfite	*Vasopressor in Shock:* *Elderly - calculated using lower dose of 2 mcg/kg/min.* *Adult - calculated using upper dose of 50 mcg/kg/min.*		
		IV Infusion	2.1 mg/hr	52.5 mg/hr
Epinephrine, 0.1 mg/mL (Abbott)	0.46 mg/mL Sodium Metabisulfite	*Vasopressor for Resuscitation: 1 mg every 5 min.*		
		Bolus every 5 min	4.6 mg	4.6 mg
Hydrocortisone Sodium Phosphate, 50 mg/mL (MSD)	3.2 mg/mL Sodium Bisulfite	*Adrenal Cortical Steroids:* *Elderly - calculated using lower dose of 15 mg/day* *Adult - calculated using upper dose of 240 mg/day*		
		Dosed every 12 hrs	0.32 mg	5 mg
Aminosyn-PF 10% (Abbott)	230 mg/100 mL Sodium Hydrosulfite	*500 mL/8 hr*		
		TPN	144 mg/hr	144 mg/hr

Table 5 below summarizes the our assessment of other parenteral drugs with comparable sulfite exposure levels correlated to the methods of administration for Propofol Injectable Emulsion to adult and elderly patients.

Table 5

Propofol Injectable Emulsion Method of Administration		**Other Parenteral Drugs with Comparable Sulfite Exposure Levels**
General Anesthesia in Elderly and Adult		
Intermittent Bolus	12.5 mg	Range: 12.5 - 14 mg Gallamine Triethiodide Tubocurarine Chloride
Induction	2.6 mg & 4.4 mg	Range: 4.6 - 14 mg Gallamine Triethiodide Tubocurarine Chloride Epinephrine Hydrocortisone Sodium Phosphate
Maintenance	10.5 mg/hr & 21 mg/hr	Range: 53 - 144 mg/hr Intropin (dopamine) Total Parenteral Nutrition Products (Amino Acids)
MAC Sedation in Adult and Elderly		
Induction	0.88 mg	Range: 4.6 - 14 mg Gallamine Triethiodide Tubocurarine Chloride Epinephrine Hydrocortisone Sodium Phosphate
Maintenance	6.3 mg/hr & 7.2 mg/hr	Range: 53 - 144 mg/hr Intropin (dopamine) Total Parenteral Nutrition Products (Amino Acids)

Based upon our assessment provided in **Table 4** and the data summarized in **Table 3**, the safety of sulfite exposure for adult and elderly patients when administered Propofol by intermittent bolus (12.5 mg), induction for general anesthesia (2.6 - 4.4 mg), and induction for MAC sedation (0.88 mg) are supported by the exposure levels which range from 4.6 to 14 mg for the approved products evaluated. When examining the sulfite exposure levels for patients administered propofol for the maintenance of general anesthesia and MAC sedation, our product is expected to deliver 6.3 - 21 mg/hr of sulfite compared to 53 - 144 mg/hr for the approved products.

Therefore, the sulfites levels due to adult and elderly doses of our proposed Propofol when used in general anesthesia and MAC sedation are equivalent or lower to sulfite

levels expected for previously approved products.

Risk Assessment - Sodium Metabisulfite vs. EDTA

As previously discussed in the section, "Sulfite Hypersensitivity," the risk is well known and well recognized as established by FDA in the 1980's. The safety of Propofol with sodium metabisulfite for long term administration is supported by the extended use of sulfite-containing amino acid TPN products. From the previous discussions, we determined that the sulfite exposure levels from Gensia Sicor's' Propofol would be less than levels contributed by the TPN products evaluated. Based upon sulfite exposure levels expected from administration of our Propofol for general anesthesia, equivalent sulfite exposure levels were determined from the dosing of approved drugs, specifically, Gallamine and Tubocurarine. In addition, the regulatory requirement to include the warning statement mitigates the risk associated with sulfites. The clinician is alerted to the potential effects of sulfites via the labeling. Since Propofol is administered for purposes of surgery, MAC sedation, or ICU sedation in a hospital setting under continuous medical monitoring, the patient is assured of immediate medical attention should a hypersensitivity reaction occur.

Sulfite preservatives are included in the formulations of many FDA-approved drug products.[12] In December 1986, FDA disagreed with a complete prohibition of the use of sulfites, however acknowledged that people should be provided sufficient information to avoid sulfites. Gensia Sicor is aware that sodium metabisulfite presents an inherent risk, especially to an asthmatic sub-population, as an additive in formulation of Propofol Injectable Emulsion. However, the limited preservative effect resulting from the presence of sodium metabisulfite accede to health benefits of the general public and outweigh the risk of sulfite hypersensitivity.

EDTA is also an inactive ingredient included in the formulations of many FDA-approved drug products. However, at the levels indicated in Zeneca's Diprivan (propofol) Injectable Emulsion with 0.005% EDTA, FDA recognized a potential risk of zinc depletion and mild renal damage due to long term exposure to EDTA from administration of Diprivan Injectable Emulsion for ICU use.[13, 14] Due to these potential risks, Zeneca was requested to add the following warning statement to the Diprivan

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[12] *Inactive Ingredient Guide (January 1996).* Division of Drug Information Resources, Office of Management, CDER, FDA.

[13] I.L. Tyler, Ph.D., M.D. Medical Officer Review NDA Report Propofol with 0.005% EDTA. Summary Basis of Approval for Diprivan Injectable Emulsion with 0.005% EDTA.

[14] Robert F. Bedford, M.D. Medical Officer Secondary Review. Summary Basis of Approval for Diprivan Injectable Emulsion with 0.005% EDTA.

product insert as follows:

> EDTA is a strong chelator of trace metals - including zinc. Calcium disodium edetate has been used in gram quantities to treat heavy metal toxicity. When used in this manner it is possible that as much as 10 mg of elemental zinc can be lost per day via this mechanism. Although with Diprivan Injectable Emulsion there are no reports of decrease zinc levels or zinc deficiency-related adverse events, Diprivan Injectable Emulsion should not be infused for longer than 5 days without providing a drug holiday to safely replace estimated or measured urine zinc losses.
>
> At high doses (2 - 3 grams per day), EDTA has been reported, on rare occasions, to be toxic to the renal tubules. Studies to date, in patients with normal or impaired renal function have not shown any alteration in renal function with Diprivan Injectable Emulsion containing 0.005% disodium edetate. In patients at risk for renal impairment, urinalysis and urine sediment should be checked before initiation of sedation and then be monitored on alternate days during sedation.
>
> The long-term administration of Diprivan Injectable Emulsion to patients with renal failure and/or hepatic insufficiency has not been evaluated.[15]

In addition due to FDA's concern regarding the potential risks of extended exposure to EDTA in an ICU setting, FDA informed Zeneca that approval of the EDTA formulation of Diprivan would be predicated upon a commitment from the company to perform a Phase IV Safety study to evaluate zinc loss and renal function in ICU patients.

In summary, sodium metabisulfite as an additive in parenteral drug products presents a known but limited risk of producing a hypersensitivity reaction, predominantly in chronic asthmatics. EDTA as an additive in an injectable at the levels defined in Zeneca's formulation of Diprivan presents an unknown risk. However, we understand that a phase IV safety study was requested by FDA to determine the level of risk associated with this exposure level of EDTA. The potential risks recognized by FDA are zinc depletion and mild renal damage. We trust that FDA is monitoring Zeneca for compliance with Zeneca's phase IV commitments.

Conclusion

We trust that the information provided herein, in conjunction with the information submitted to the Agency in correspondence dated July 17, 1997, June 15, and June 20, 1998, is adequate to support the Agency's decision that the substitution of sodium metabisulfite for edetate disodium as the preservative in our Propofol Injectable Emulsion does not affect the safety of our proposed product.

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[15] Warnings section of package insert of Diprivan Injectable Emulsion with 0.005% EDTA.

Should you have any questions or would like to further discuss this matter, please do not hesitate to contact me at (949) 455-4716. We will call you on Wednesday, August 26, to follow up on your meeting with the Office of New Drug Evaluation regarding this matter.

Sincerely,

Armand J. LeBlanc
Vice President, Scientific Affairs

Attachments

cc: Mr. Donald B. Hare - Office of Generic Drugs
Dr. Cynthia McCormick - Anesthetic, Critical Care & Addiction Drug Products
Dr. Roger Williams - Pharmaceutical Science

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Professional Corporations
600 13th Street, N.W.
Washington, D.C. 20005-3096
202-756-8000
Facsimile 202-756-8087
http://www.mwe.com

David L. Rosen
Attorney at Law
drosen@mwe.com
202-756-8075

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McDERMOTT, WILL & EMERY

August 10, 1998

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NDA CORRESP

VIA FACSIMILE AND FEDERAL EXPRESS

ANDA 75-102

Mr. Douglas Sporn
Director
Office of Generic Drugs, HFD-600
Metro Park North II
Center for Drug Evaluation and Research
Food and Drug Administration
7500 Standish Place
Rockville, Maryland 20855

Re: Telephone Conference with GensiaSicor Pharmaceuticals, Inc. Regarding the Use of Sodium Metabisulfite as a Preservative in its Propofol Injectable Emulsion, 10mg/mL

Dear Mr. Sporn:

I am writing to you on behalf of our client, GensiaSicor Pharmaceuticals, Inc. to request and confirm telephone conference with representatives of the Office of Generic Drugs ("OGD") and Dr. Roger Williams of the Office of Pharmaceutical Science to present and discuss additional information supporting the conclusion that the difference in preservative used by GensiaSicor does not affect the safety of the proposed product.

GensiaSicor is requesting that the teleconference be scheduled before August 25, the date on which I understand that there will be a meeting of CDER staff to discuss this matter. The additional information to be presented and discussed further supports the material previously submitted by GensiaSicor that the substitution of sodium metabisulfite for edetate sodium as a preservative does not affect the safety of Propofol Injectable Emulsion.

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As this matter is of the utmost importance to GensiaSicor, we appreciate your accommodation of this request. I will call you later this week to arrange a date and time for the telephone conference.

Attendees. The following people will participate in the telephone conference:

GensiaSicor Pharmaceuticals, Inc.

Armand J. LeBlanc, Vice President, Scientific Affairs

Rosalie Lowe, Associate Director, Regulatory Affairs

Consultants

Meeting Agenda. The proposed agenda for the telephone conference is as follows:

1. Brief Introduction

2. Review of the Difference in Preservative Systems Between the GensiaSicor and Reference Listed Product

3. Review of Safety and Clinical Impact Concerning the Use of Sodium Metabisulfite as a Preservative in Propofol Injectable Emulsion

4. Discussion of GensiaSicor's ANDA

I appreciate your assistance in arranging the telephone conference and look forward to the discussion. Again, I will call you later this week to confirm the date and time for telephone conference. Of course, please do not hesitate to call me at (202) 756-8075 if you need any further information.

Sincerely yours,

David L. Rosen

cc: Armand J. LeBlanc
Rosalie Lowe
GensiaSicor Pharmaceuticals, Inc.

Rita Hassall, OGD
Gordon Johnston, OGD
Ted Sherwood, OGD

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NEW CORRESP

June 30, 1998

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Exempt from Disclosure
Under FOIA

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation Control Room 150
7500 Standish Place
Rockville, MD 20855-2773

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RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Containing 0.025% Sodium Metabisulfite
Technical Response to Citizens Petition 98P-0221/PSA 1

GENERAL CORRESPONDENCE

Dear Mr. Sporn:

Reference is made to Docket No. 98P-0221/PSA 1, the citizens petition (the "Petition") submitted by Stephen Mahinka, Esq., counsel to Zeneca Inc., to stay the effective date of pending, tentative, or final decisions to approve ANDAs for certain generic versions of Diprivan® (Propofol) Injectable Emulsion.

We have provided a "General Response" to the Petition which was submitted to the Dockets Management Branch on June 30, 1998, to support the position that the Commissioner deny the Petitioner's request (a copy of this response is enclosed as **Attachment 1**). This "General Response" provides adequate justification for the Commissioner to deny the Petitioner's request. However, in the "General Response" we have not addressed the specific technical issues related to our sodium metabisulfite formulation of propofol. As you know, Gensia Sicor has submitted paragraph IV certification in this ANDA. In addition, Gensia Sicor has sent notice to Zeneca stating that, in our opinion, and to best of our knowledge, our Propofol Injectable Emulsion with a preservative other than EDTA does not infringe Zeneca's patents pertaining to Diprivan® with EDTA. In such notices to Zeneca, we have not disclosed the preservative used in our product. Consequently, due to the confidential nature of this information, Gensia Sicor has decided to respond to these technical issues within our

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

CONFIDENTIAL

ANDA. Therefore, the information contained within this submission will provide the Agency with Gensia Sicor's position with respect to the technical issues brought forth in the aforementioned Petition.

Furthermore, since this technical response contains confidential, commercial, and trade secret information and data, in our opinion, it is exempt from public disclosure. Should you believe otherwise, we request that you notify us prior to disclosing any information concerning the preservative in our propofol product.

Clearly, the Petitioner and Zeneca are once again attempting to block entry of a legitimate generic product in an effort to maintain Zeneca's monopoly of the propofol market. This is evidenced by the fact that the Petition does not direct the Agency to undertake any additional administrative action beyond those defined within the existing statutes and regulations. Pursuant to these statutes and regulations, FDA will appropriately rule to approve or deny an application based upon relevant scientific review of the application to determine the safety and efficacy of a drug product. However, we recognize that the Petition provides points-to-consider with respect to review of an application for a propofol formulation containing an alternate preservative. It is to these specific points that we wish to respond.

Gensia Sicor wishes to defend its application in light of the issues raised by the Petitioner. Accordingly, we request the opportunity to meet with the Agency to discuss these latest developments no later than July 31, 1998. I will call your office next week to arrange a mutually convenient date and time for the meeting. In the interim, if additional information is required or if there are any questions concerning this matter, please do not hesitate in contacting me at (949) 455-4716.

Sincerely,

Armand J. LeBlanc
Vice President, Scientific Affairs

Enclosure

cc: Mr. Gordon Johnson
Mr. Don Hare
Mr. Peter Rickman
Office of Generic Drugs

Ms. Elaine Messa
Los Angeles District

Ms. Paula Botstein, MD
Office of Drug Evaluation III

Ms. Cynthia McCormick, MD
Division of Anesthesiology, HFD 170

GensiaSicor™
PHARMACEUTICALS
A GensiaSicor Company

NEW CORRESP

May 27, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025%
Sodium Metabisulfite

RECEIVED

AMENDMENT

MAY 28 1998

GENERIC DRUGS

Dear Mr. Sporn:

Reference is made to our abbreviated new drug application for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite, ANDA 75-102. Further reference is made to the two amendments, which contained Paragraph IV Patent Certification Statements, dated February 11, 1998 and April 13, 1998.

In accordance with the provisions of Section 314.95(e) of the *Code of Federal Regulations, Title 21*, we hereby amend this application. We wish to document receipt of the notices as required under paragraph (a) of Section 314.95 by three of the four entities provided the notices. Copies of the return receipts are attached. Please note that the Return Receipt requested of the U.S. Postal Service (USPS) for the notice regarding Patent No. 5,714,520, which was sent to Zeneca Ltd. in the United Kingdom on February 11, 1998, has not been returned. A trace to locate the document was placed with the USPS on April 17, 1998, however, USPS has been unsuccessful in obtaining the Return Receipt to date. Therefore, it is our contention that Zeneca Ltd. received adequate notice since a Return Receipt was received from Zeneca Inc. in Wilmington, Delaware. In addition, Zeneca formally responded to our notice by filing a lawsuit on April 3, 1998, which was subsequently withdrawn.

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the attached documentation satisfactory. Should you have any questions or require further clarification, please contact me at (949) 457-2808 or by facsimile at (949) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

Attachments
S:\PRO7510Z\AMEND6\AMEND6.WPD

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

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VIA FACSIMILE AND FEDERAL EXPRESS MAIL

NEW CORRESP NAI 4/20/4

April 13, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite.

At this time we wish to submit a updated Patent/Exclusivity Statement which provides a certification statement regarding the two patents granted Zeneca Ltd. on March 24, 1998, for Diprivan®. The referenced information was obtained on April 3, 1998, from FDA's web site at http://www.fda.gov/cder/orange/docket.pdf.

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APR 14 1998
GENERIC DRUGS

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Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (714) 455-4724 or by facsimile at (714) 583-7351. (Please be advised that our area code will change from "714" to "949" on April 18, 1998.)

Sincerely,

Elvia O. Gustavson

Elvia O. Gustavson
Associate Director, Regulatory Affairs

Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

Mr. Peter Rickman
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-615
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

GensiaSicor™
PHARMACEUTICALS

March 12, 1998

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia Sicor's amendment to ANDA 75-102 for Propofol Injectable Emulsion (with 0.025% Sodium Metabisulfite), 10 mg/mL, which was submitted January 16, 1998. Reference is also made to a telephone conversation on February 12, 1998, between Mr. Ray Brown, Chemistry Reviewer in the Office of Generic Drugs, and myself regarding the submission of referenced information from ANDA 74-816. Mr. Brown's request is intended to consolidate all relevant information within a single application. As agreed, we have provided all sections of the ANDA 75-102 which previously included references to ANDA 74-816.

Therefore, in accordance with Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby amend this application (ANDA 75-102) for Propofol Injectable Emulsion (with 0.025% Sodium Metabisulfite), 10 mg/mL, with additional information. These revised sections provided herein supersede all previous information submitted for these specific sections of the ANDA.

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MAR 16 1998
GENERIC DRUGS

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Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com
100003

The sections listed below were previously referenced by incorporation and were not included in the amendment dated January 16, 1998. These sections are provided in this amendment.

Section IX	Description of Manufacturing Facility
Section X	Outside Firms Including Contract Testing Laboratories
Section XIII	Packaging and Labeling Procedures
Section XVIII	Control Numbers
Section XX	Environmental Impact Statement
Section XXI	Other

In addition, **Section XI** and **Section XVI** has been provided in their entirety. Please note that these sections were submitted previously, but included several references to ANDA 74-816.

Finally, **Section 3** of the Sterility Assurance Validation package has also been revised to include the information referenced in ANDA 74-816.

The amendment consists of two (2) volumes and has been formatted in accordance with the Office of Generic Drug's Policy and Procedure Guide #30-91 issued April 10, 1991; and, as modified by FDA's October 14, 1994 letter to all NDA, ANDA, and AADA applicants. Copies are provided as follows:

1) One (1) Archival Copy bound in Blue Jackets
2) One (1) Review Copy bound in Red Jackets

A true copy of this amendment, which was bound in Burgundy Jackets, has been submitted to the U.S. Food and Drug Administration of Irvine, California, District Office.

Since **Section XVI** has been provided in its entirety, three (3) complete methods validation packages (i.e., packages which include information referenced in ANDA 74-816) have been included and are marked "Analytical Methods." These three additional copies are identical to **Section XVI** as presented in the archival and review copies, and have been separately bound in Black Jackets.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting myself at (714) 457-2808.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

GensiaSicor™
PHARMACEUTICALS

NEW CORRESP
NC

February 11, 1998

VIA FACSIMILE AND FEDERAL EXPRESS MAIL

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 75-102
Propofol Injectable Emulsion, 10 mg/mL
Formulation Containing 0.025% Sodium Metabisulfite

AMENDMENT

Dear Mr. Sporn:

Reference is made to Gensia's Abbreviated New Drug Application (ANDA 75-102) for Propofol Injectable Emulsion containing 0.025% Sodium Metabisulfite. Reference is also made to a telephone conversation on February 2, 1998 between myself and Ms. Margo Bartel, Office of Generic Drugs, FDA, regarding the Patent/Exclusivity Statement provided in our application.

Ms. Bartel requested that Gensia Sicor amend its application for Propofol Injectable Emulsion (0.025% Sodium Metabisulfite) to include a certification statement for the new patent which was recently granted the innovator, Zeneca Ltd., for their formulation of propofol containing EDTA. Pursuant to Ms. Bartel's request, the Patent/Exclusivity Statement (Section III) has been revised and is included in this amend

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GENERIC DRUGS

GensiaSicor Pharmaceuticals • 17 Hughes • Irvine CA • 92618-1902 • USA
Phone (714) 455-4700, (800) 729-9991 • Fax (714) 855-8210 • http://www.gensiasicor.com

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this amendment, please do not hesitate in contacting me at (714) 457-2808 or by facsimile at (714) 583-7351.

Sincerely,

Rosalie A. Lowe

Rosalie A. Lowe
Associate Director, Regulatory Affairs

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Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Blvd., Suite 300
Irvine, CA 92715

Mr. Peter Rickman
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-615
Attention: Documentation and Control Room, Room 150
7500 Standish Place
Rockville, MD 20855-2773

GENSIA
LABORATORIES LTD

December 3, 1997

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion
(with 0.005% EDTA), 10 mg/mL
Prefilled Syringe
ANDA: 75-102

MINOR AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing 0.005% Disodium Edetate (EDTA) in the formulation, ANDA 75-102. Reference is also made to the Agency's letter dated October 22, 1997. In accordance with the provisions of Section 314.96 of the Code of Federal Regulations, Title 21, we hereby amend our application to provide the additional information as requested.

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

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Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92618 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0095

GENSIA
LABORATORIES, LTD.

NEW CORRESP

N C

May 20, 1997

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion
(with 10 mg/mL
Prefilled Syringe
ANDA: 75-102

AMENDMENT

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing e formulation, ANDA 75-102. Reference is also made to the Agency's letter dated May 8, 1997 regarding the Patent/Exclusivity Statement (Section III, Volume 1) provided in this application. In accordance with the provisions of Section 314.96 of the Code of Federal Regulations, Title 21, we hereby amend our application to provide the additional information as requested.

The Patent/Exclusivity Statement (Section III) was revised to include the new exclusivity date of June 11, 1999 for Zeneca's new product. Page 13 from the *Approved Drug Products with Therapeutic Equivalence Evaluations, 17th Edition*, Supplement 1, January 1997, which lists the new exclusivity date is also included.

Section III of the ANDA which was revised is being provided in its entirety. To facilitate your review, text changes have been redlined. All other pages within the section remain identical to the original ANDA submission.

RECEIVED
MAY 21 1997
GENERIC DRUGS

Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92718-1902 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0393
Gensia Europe, Ltd. ■ Genaresa House ■ 1 Bracknell Beeches, Old Bracknell Lane, Bracknell, Berkshire RG127BW
44-344-308803 ■ FAX 44-344-360515

We trust you will find the information in this amendment satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

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Enclosure

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

ANDA 75-102

Gensia Laboratories, Ltd.
Attention: Donald J. Harrigan
19 Hughes
Irvine, CA 92618

MAY 5

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Propofol Injectable Emulsion 1%, (10 mg/mL), in 20 mL syringe

DATE OF APPLICATION: March 31, 1997

DATE OF RECEIPT: April 1, 1997

We will correspond with you further after we have had the opportunity to review the application.

Please amend your application with a revised patent certification and exclusivity statement using the most current version of the Approved Drug Products with Therapeutic Equivalence Evaluations and supplement.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Kassandra Sherrod
Project Manager
(301) 827-5849

Sincerely yours,

/S/ 5/6/97

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

GENSIA
LABORATORIES, LTD.

March 31, 1997

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1997
GENERIC DRUGS

Mr. Douglas Sporn
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, HFD-600
Attention: Documentation and Control Room, Room 150
7500 Standish Place,
Rockville, MD 20855-2773

RE: Propofol Injectable Emulsion (with 0.005% EDTA), 10 mg/mL Prefilled Syringe
ANDA: Number to be Assigned

Dear Mr. Sporn:

Reference is made to a telephone conversation on December 19, 1996 between Ms. Cecilia Parise, Consumer Safety Officer, Office of Generic Drugs and myself regarding the safety issues related to the formulation of Propofol Injectable Emulsion. Ms. Parise indicated that the Agency would only accept ANDA applications for Propofol Injectable Emulsion which contain n the formulation. Therefore, pursuant to Ms. Parise's instructions and in accordance with Section 314.96(a)(1) of the *Code of Federal Regulations, Title 21*, we hereby submit an Abbreviated New Drug Application for Propofol Injectable Emulsion (Prefilled Syringe) containing in the formulation.

Propofol Injectable Emulsion (with , is a parenteral emulsion preparation to be supplied as:

Strength	Drug Content	How Supplied
10 mg/mL	200 mg Propofol Injectable Emulsion/syringe	200 mg in a 20 mL syringe

Propofol Injectable Emulsion, 10 mg/mL ., is the generic version of Diprivan® (Propofol Injectable Emulsion) which is currently manufactured by Zeneca, Ltd. Zeneca's drug product appears in the FDA listing titled *Approved Drug Products with Therapeutic Equivalence Evaluation, 16th Edition.* Our drug product has the same

Gensia Laboratories, Ltd. ■ 19 Hughes, Irvine, CA 92718-1902 ■ (714) 455-4700 ■ FAX (714) 855-8210
Gensia Inc. ■ 9360 Towne Center Drive, San Diego, CA 92121 ■ (619) 546-8300 ■ FAX (619) 453-0095
Gensia Europe, Ltd. ■ Genaresa House ■ 1 Bracknell Beeches, Old Bracknell Lane, Bracknell, Berkshire RG127BW
44-344-308803 ■ FAX 44-344-360515

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active and inactive ingredients, dosage form, strength, route of administration, and conditions of use as Zeneca's listed drug product containing

Gensia's manufacturing processes used for Propofol Injectable Emulsion supplied in a prefilled syringe are equivalent to the processes used for Gensia's product supplied in vials for the processes described in the sections listed below. Therefore, reference is made to our amendment ANDA 74-816, which was submitted December 24, 1996 with respect to these sections.

Section VI	Bioavailability/Bioequivalence
Section VII	Components and Composition Statements *
Section VIII	Raw Material Controls
Section IX	Description of Manufacturing Facility
Section X	Outside Firms Including Contract Testing Laboratories
Section XIII	Packaging and Labeling Procedures
Section XVI	Analytical Methods **
Section XVIII	Control Numbers
Section XIX	Sample Availability and Identification
Section XX	Environmental Impact Statement
Section XXI	Other

* Except as this section relates to the container
** Except for the specific lots of finished product

The table below identifies the variation from the vial amendment of ANDA 74-816 which were changed or included to differentiate the prefilled syringe product. These differences include changes to the basis for ANDA, patent certification, labeling, chemistry, manufacturing, control changes, container/closure, and stability. Documentation supporting this information are provided in the sections listed:

Section	Variations from ANDA 74-816 Amendment	Supporting Documentation
II	A summary of the supporting stability lot.	Tables summarizing the information. Reference to **Section XI** for the stability lot.
III	Patent certification and exclusivity statements submitted to reflect current status of the innovator's product.	Orange Book reference.

Section	Variations from ANDA 74-816 Amendment	Supporting Documentation
IV	Comparison between Gensia's versus Zeneca's products for propofol ormulations supplied in a prefilled syringe.	Table summarizing the comparison between Gensia's and the innovator's formulations supplied in a prefilled syringe.
	Comparison between Gensia's versus Zeneca's labeling for both propofo ilations supplied in a prefilled syringe.	Side-by-side comparison of Gensia's versus Zeneca's labeling for both propofol EDTA formulations supplied in a prefilled syringe.
V	Labeling for Gensia's Propofol Injectable Emulsion	Draft labeling.
VII	Components and composition statements to reflect the 20 mL prefilled syringe container.	Components and composition statements, and tables for Propofol Injectable Emulsion (with
XI 1.	Summary for manufacturing and processing which reflect the filling of Propofol Injectable Emulsion (with in a prefilled syringe.	The compounding procedure and manufacturing flow diagram for Propofol Injectable Emulsion
	Sterility assurance of the product references volume 4.	Specific sterility assurance information for the manufacture of Propofol Injectable Emulsion plied in prefilled syringe.
2.	Blank batch records which specific for the prefilled syringe product.	Blank batch records for the 20 mL prefilled syringe.
XII	One stability lot to support the prefilled syringe product.	Copies of the executed batch records for the stability lot of Propofol Injectable Emulsion): Lot No. XP6C319F2.
	Finished Product Sampling Plans specific to the prefilled syringe product.	**Finished Product Sampling Plan** for Propofol Injectable Emulsion (with

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Section	Variations from ANDA 74-816 Amendment	Supporting Documentation
XV	**Finished Product Specifications and Data Sheet** specific to the prefilled syringe product.	Blank current **Finished Product Specifications and Data Sheet.**
	Stability lot of the prefilled syringe product.	**Finished Product Specifications and Data Sheet** for the stability lot.
XVI	**Finished Product Specifications and Data Sheet** specific to the prefilled syringe product.	Blank current **Finished Product Specifications and Data Sheet.**
	Stability lot of the prefilled syringe product.	**Finished Product Specifications and Data Sheet** for the stability lot.
XVII	One stability lot of the 20 mL prefilled syringe was manufactured and stability data is presented. In addition, the 20 mL vial lot (Lot No. XP6N319), which is the subject of ANDA 74-816, is presented in support of the stability section of this application.	Stability Report

Four copies of the proposed labeling have also been provided in **Section V** of the application in both the archival and review copies.

The application consists of four (4) volumes and has been formatted in accordance with the Office of Generic Drug's Policy and Procedure Guide #30-91 issued April 10, 1991; and, as modified by FDA's October 14, 1994 letter to all NDA, ANDA, and AADA applicants. Copies are provided as follows:

1) One (1) Archival Copy bound in Blue Jackets
2) One (1) Review Copy bound in Red Jackets

A true copy of this application, which was bound in Burgundy Jackets, has been submitted to the U.S. Food and Drug Administration of Irvine, California, Los Angeles District Office.

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Since the product which is the subject of this application is non-compendial, three (3) additional methods validation packages have been included and are marked "Analytical Methods." These three additional copies are identical to **Section XVI** as presented in the archival and review copies, and have been separately bound in Black Jackets.

We trust you will find the information in this application satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate in contacting Ms. Rosalie A. Lowe, Associate Director, Regulatory Affairs, at (714) 457-2808, or myself at (714) 455-4709, or by facsimile at (714) 583-7351.

Sincerely,

Donald J. Harrigan

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

cc: Ms. Elaine Messa
District Director
U.S. Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92715

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Field Copy Certification

Gensia Laboratories, Ltd., certifies that a true copy of our application for Propofol Injectable Emulsion), 10 mg/mL, Prefilled Syringe, which was submitted to the Agency on March 31, 1997, was also provided to the Irvine, California, Los Angeles District Office of the U.S. Food and Drug Administration.

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

3/31/97
Date

Debarment Certification

As required by the Generic Drug Enforcement Act of 1992, Gensia Laboratories, Ltd., certifies that we did not and will not use in any capacity the services of any person debarred under subsections (a) or (b) [section 306 (a) or (b)] of the Act, in connection with our application for Propofol Injectable Emulsion (with 0.005% EDTA), 10 mg/mL, Prefilled Syringe.

We are unaware of any convictions of crimes (as specified in section 306 (a) and (b) of the Act) within the previous five years of any Gensia employees or affiliated company, or employees of the affiliated companies responsible for the development or submission of this abbreviated application for Propofol Injectable Emulsion (with 0.005% EDTA), 10 mg/mL, Prefilled Syringe.

Donald J. Harrigan, R.Ph.
Director, Regulatory Affairs

3/31/97
Date

Glen J. Lerner, Esq.
Nevada Bar No. 4314
GLEN LERNER INJURY ATTORNEYS
4795 South Durango Drive
Las Vegas, Nevada 89147
Telephone: (702) 877-1500
Facsimile: (702) 307-5762
E-mail: glerner@glenlerner.com

Peter C. Wetherall, Esq.
WETHERALL GROUP, LTD.
Nevada Bar No.: 4414
9345 W. Sunset Rd., Ste. 100
Las Vegas, NV 89148
Telephone: (702) 838-8500
Facsimile: (702) 837-5081
E-mail: pwetherall@wetherallgroup.com

Attorneys for Plaintiffs

DISTRICT COURT

CLARK COUNTY NEVADA

ABADJIAN, SOSSY, et al., Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC.; SICOR, Inc., a Delaware Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware Corporation; McKESSON MEDICAL-SURGICAL INC., a Delaware Corporation, Defendants.	Case No.: A-18-781820-C Dept. No.: 4 **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS** Hearing Date: October 22, 2019 Hearing Time: 9:00 a.m.

Plaintiffs, by and through their attorneys of record, Glen J. lerner of Glen Lerner Injury Attorneys and Peter C. Wetherall, Esq., of Wetherall Group, Ltd., hereby submit their Opposition to Defendants' Motion to Dismiss. Said Opposition is made and based on the following Memorandum

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. . .

. . .

. . .

of Points and Authorities, the exhibits thereto, the pleadings and papers filed herein, and all other matters properly of record. [1]

GLEN LERNER INJURY ATTORNEYS

By:/s/ Glen J. Lerner
Glen J. Lerner, Esq.
Nevada Bar No. 4314
4795 South Durango Drive
Las Vegas, Nevada 89147

WETHERALL GROUP, LTD.
Peter C. Wetherall, Esq.
Nevada Bar No.: 4414
9345 W. Sunset Rd., Ste. 100
Las Vegas, NV 89148
E-mail: pwetherall@wetherallgroup.com
Attorney for Plantiffs

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION:

Defendants' Motion to Dismiss contains no acknowledgement *whatsoever* of Defendants' well-documented wrongdoing, no acknowledgement of the multiple Clark County "Endoscopy" verdicts (and settlements) obtained against these Defendants which confirm their wrongdoing, and no acknowledgement of the fact that multiple judges in this jurisdiction have already heard and resolved Defendants' preemption arguments in Plaintiffs' favor (both before and after the aforementioned trials).

Defendants' Motion further contains no acknowledgement that Judges Mahan and Navarro of the Federal District Court similarly *rejected* Defendants' preemption arguments only weeks ago when remanding this and two companion cases back to state court. Lastly, Defendants' Motion does not bother informing this Court that District Judge Crockett denied this Motion *in its entirety* at a hearing argued before him on September 17 in the *Bridges* case (Order pending). [2]

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[1] The undersigned Counsel recognizes that the inclusion of exhibits outside the pleadings is normally inappropriate in this context, but in light of the arguments and exhibits proffered in Defendants Motion, Plaintiffs urge the Court to take Judicial Notice of Plaintiffs' exhibits as well.

[2] There are hundreds of other Endo "non-infected" Plaintiffs in two other Complaints which were also removed to federal court and thereafter returned on Plaintiffs' Motions to Remand. The other two cases are *Bridges*, et al., proceeding in Dept. 24, and *Adams*, et al., proceeding in Dept. 8.

Against this audacious backdrop, Defendants seek this Court's Order dismissing Plaintiffs' claims and depriving them of any measure of justice for the harm done to them, which is admittedly less harm than that suffered by the Hepatitis-infected victims, but nevertheless significant.

Selling FDA-approved single-dose vials (as opposed to multi-use vials) does not render it impossible for Defendants' to comply with the United States Federal Food, Drug, Device and Cosmetic Act ("FDCA") and Nevada state law. This is a design defect case with no sustainable impossibility preemption defense available to these Defendants **under these circumstances**. For these reasons, Defendants' Motion should be denied.

II. STATEMENT OF FACTS:

Plaintiffs herein constitute but a handful of the tens of thousands of recipients of the CDC/SNHD letters sent in 2008 which warned Endoscopy Center patients who treated at specific Gastroenterology Centers in Clark County, Nevada of possible infection with Hepatitis B, Hepatitis C, and HIV. CDC Press Release, **Exh. 1**. Plaintiffs herein were encouraged by that letter – and the ensuing publicity this public health catastrophe occasioned – to get tested for these communicable infections. Plaintiffs herein dutifully obtained the necessary testing, and remained in mortal fear of a life-altering infection until such time as their testing sufficiently confirmed no infection. Thus, Plaintiffs are all "non-infected Endoscopy Plaintiffs" who have sued to obtain compensation for the costs of their testing as well as the pain and suffering associated with their need to be tested, sometimes retested, and awaiting the results before being assured they and their loved ones did not suffer the fate of actual infection created by the aforementioned outbreak which befell so many others. Plaintiffs' cases were all tolled until recently, when the Parties' longstanding efforts to reach a settlement resulted in impasse.

This lawsuit was originally filed in state court on September 27, 2018. Defendants removed this case to federal court on December 10, 2018. Defendants specifically cited in their Notice of Removal "impossibility preemption" as one reason why this case belonged in federal court. Immediately thereafter, on December 17, 2018, Defendants filed a Motion to Dismiss **virtually identical to the instant Motion** in the *Bridges* non-infection case (also filed by the undersigned

counsel, identical to this one except with different Plaintiffs, and also removed) premised predominantly on "impossibility preemption".

Plaintiffs filed their Motion for Remand on January 9, 2019, based solely upon Defendants' failure to meet the amount in controversy requirement for federal jurisdiction. In response, Defendants filed their Opposition to Plaintiffs' Motion to Remand on January 23, 2019, again arguing extensively that "impossibility preemption" not only warranted federal court jurisdiction, but also the dismissal of Plaintiffs' lawsuit entirely. This was an admittedly clever strategy on Defendants' part – to telegraph to the federal court judges that they could assume jurisdiction over these cases only to then clear their dockets of them on preemption grounds, but it backfired.

While Plaintiffs' Motion to Remand was pending, the Parties stipulated to stay briefing on Defendants' Motion to Dismiss, as that Motion would be rendered moot (in federal court) if remand back to state court was granted. Thereafter, on April 12, 2019, the Federal District Court, Honorable James C. Mahan presiding, entered an Order granting remand in the *Bridges* case. On August 23, 2019, Judge Mahan entered an Order granting remand in this case. On August 26, 2019, the Federal District Court, Chief Judge Gloria M. Navarro presiding, entered an Order granting remand in the *Adams* case. In each Order granting remand, the Court felt compelled to address Defendants' multiple efforts to argue that "impossibility preemption" not only justified federal jurisdiction, but the outright dismissal of Plaintiffs' Complaint. In his two Orders, Judge Mahan stated:

> The court notes that defendants' arguments are unclear, incoherent, and at times confused. **Some paragraphs from defendants' brief appear to assert that the court has jurisdiction because the FDCA preempts plaintiffs' state law claims. To ensure complete adjudication of all pertinent issues that the parties raise, the court will consider this argument**.
>
> The "complete preemption doctrine" allows district courts to exercise federal question jurisdiction over state law claims when a federal statute completely preempts the relevant state law. *Balcorta v. Twentieth Century-Fox Film Corp.*, 208 F.3d 1102, 1107 (9th Cir. 2000) (citation omitted). Courts consider the factual allegations in the complaint and the petition of removal to determine whether federal law completely preempts a state law claim. *Schroeder v. Trans World Airlines, Inc.*, 702 F.2d 189, 191 (9th Cir. 1983).
>
> It is well established that the FDCA does not completely preempt state law. *See Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1259–60 (D. Or. 2011); *see also Perez v. Nidek Co. Ltd.*, 657 F. Supp. 2d 1156, 1161 (S.D. Cal. 2009); *see also Alaska v. Eli Lilly & Co.*, No. 3:06-cv-88 TMB, 2006 WL 2168831 at *3–4 (D. Ala July 28, 2006).

Therefore, the court does not have federal question jurisdiction under the complete preemption doctrine.

See Order [Granting Remand] in *Bridges*, dated April 12, 2019, attached hereto as **Exh. 2**, at 6:8-22 (bold and underline emphasis added).

Judge Mahan went on to conclude, "[T]he FDCA does not completely preempt plaintiffs' state law claims." *Id*., at 8:26. Judge Mahan's Order in this case is near identical. *See* Order [Granting Remand], dated August 23, 2019, attached hereto as **Exh. 3**, at 6:25-7:11; and 7:15.

Judge Navarro independently reached the same conclusions in the *Adams* case, albeit while also citing Judge Mahan's Order in *Bridges* with approval. *See* Order [Granting Remand] in *Adams*, dated August 26, 2019, attached hereto as **Exh. 4**, at 9:7-10; see also 8:1-9:16.

Immediately upon the remand of the *Bridges* case, Defendants again sought to ply their preemption arguments in state court in an identical Motion to Dismiss as has now been filed here and in *Adams*. Judge Crockett denied Defendants' Motion to Dismiss in *Bridges* at a hearing occurring on September 17, and the Order from that ruling is now pending. **In sum, Defendants are serially pursuing their preemption grounds for dismissal, despite two federal judges (on three occasions) and one district judge ruling against them thus far.**

Consistent with prior lawsuits filed in this litigation, Plaintiffs' Complaint asserts claims for: 1) strict products liability; 2) breach of the implied warranty of fitness for a particular purpose; 3) negligence; 4) violation of the Nevada Deceptive Trade Practices Act; and 5) punitive damages.

III. LEGAL ARGUMENT

A complaint should be dismissed for failure to state a claim "only if it appears beyond a doubt that [the plaintiff] could prove no set of facts, which, if true, would entitle [the plaintiff] to relief." *Alcantara ex rel. Alcantara v. Wal-Mart Stores, Inc.*, 130 Nev... 252, 256, 321 P.3d 912, 914 (2014), citing *Buzz Stew, L.L.C. v. City of N. Las Vegas*, 124 Nev. 224, 227–28, 181 P.3d 670, 672 (2008).

Defendants' arguments for dismissal boil down to four assertions: First, "Defendants were not the wrongdoers". *See* Motion, at 1:19. Second, "every claim against Defendants must be dismissed because they are preempted by federal law" pursuant to the doctrine of "impossibility preemption". *Id*., at 1:19-21, 2:16. Third, in the alternative, each of Plaintiffs' causes of action are

"missing the essential element of causation or is otherwise invalid as a matter of law". *Id*., at 3:16-17. Fourth, 167 of the 229 named Plaintiffs in this case were not a party to the tolling agreement, *Id*., at 19-21.

Regarding Defendants' Fourth grounds for dismissal of the 167 Plaintiffs not on the tolling agreement, Plaintiffs hereby stipulate to the dismissal of any non-tolled Plaintiffs from this Complaint. As for Defendants' other three grounds for dismissal, none have merit and all should therefore be denied for the reasons that follow.

A. DEFENDANTS ARE CONFIRMED WRONGDOERS WITH REGARD TO THE SALE AND DISTRIBUTION OF PROPOFOL TO THE SUBJECT ENDOSCOPY CLINICS.

It is incomprehensible how Defendants can contend with a straight face that they cannot and should not be liable for the harm done to Plaintiffs merely because others were criminally tried and convicted for contributing to the harm done. Defendants made this same argument while litigating and trying the infection cases, and never prevailed before any judge or jury on this point.

These Defendants' civil liability, and the Endoscopy Clinic owners/operators criminal liability, are not mutually exclusive. The bad acts of the Endoscopy Clinic owners/operators does not provide immunity to these product Defendants. Despite recounting in excruciating detail the criminal proceedings against others which paralleled the civil lawsuits brought against these Defendants, nowhere in their Motion is any case authority supporting Defendants' asserted immunity from suit for reasons relating to the various criminal convictions.

Nonetheless, Defendants urge the Court to evaluate Plaintiffs' claims "against this factual backdrop". Motion, at 7:6. That sounds like a plea for sympathy under circumstances where these Defendants are entitled to none.

The gravity of Defendants' wrongdoing is perhaps no better reflected than in the multiple verdicts and judgments obtained against them, for identical grounds as being asserted here, which constitute the largest personal injury verdicts in Nevada history. *See*, *Chanin* Judgment, dated June 1, 2010 w/Verdict(s) dated May 5 and 7, 2010, attached hereto as **Exh. 5**; *Sacks*, *Arnold*, *Devito* Judgment, dated November 16, 2011 w/Verdict(s), dated October 6 and 10, 2011, attached hereto as

Exh. 6; and *Washington* Judgment, dated October 19, 2011 w/Verdict(s) dated October 10 and 12, 2011, attached hereto as **Exh. 7**.

Notably, each of these verdicts was obtained long after the U.S. Supreme Court's seminal preemption decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), a case upon which Defendants here rely. Motion, at 8:20, 9:14. The *Sacks, et al*. and *Washington* verdicts were obtained after the U.S. Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) was handed down June 23, 2011, another case upon which Defendants rely extensively. Rather than proceeding to trial on hundreds of other infection cases, or pressing appeals against the aforementioned verdicts in order to vindicate their preemption arguments, these Defendants bought their peace for amounts "widely reported in the media to be hundreds of millions of dollars." https://armadr.com/hon-jennifer-togliatti-ret-2/.

A threshold question for this Court becomes, has anything changed between the date of Defendants' last foray into Clark County District Court and now? The answer is "no". The facts giving rise to these non-infected Plaintiffs' claims are identical to the infection cases, the claims are the same, and the cases relied upon by Defendants in seeking dismissal now are the same as those which were unsuccessfully proffered to various District Court judges previously. The only substantive difference is the damages here are less severe, because these Plaintiffs did not get infected by Hepatitis, they were "only" caused (by the actions of these Defendants) to fear infection for as long a period of time as it took their testing to clear and their concerns to be allayed. These types of damages are actionable. *Sadler v. Pacificare of Nev., Inc.*, 130Nev.990,. 340 P.3d 1264 (2014) (Non-infected Endoscopy claimants suffered a cognizable "injury" despite not being infected and can pursue damage claims, including medical monitoring).

B. "IMPOSSIBILITY PREEMPTION" DOCTRINE DOES NOT IMMUNIZE DEFENDANTS FROM LIABILITY HERE.

In the case at bar, Judge Mahan's Order granting remand has already concluded that Plaintiffs' claims are not preempted. In previous Endoscopy cases litigated after the *Pliva* decision, the District Court has already concluded that federal preemption does *not* bar Plaintiffs' claims.

See, Decision and Order: Plaintiffs' Motion for Partial Summary Judgment on Preemption Defense for the Dear Doctor Liability … Product Defendants' Pre-Trial Motion #4, Motion for Summary Judgment on Grounds of Federal Preemption on Order Shortening Time, *Sacks, et al. v. Endoscopy Center of Southern Nevada, LLC, et al.*, Dist. Ct. Case # 08A572315 (Consolidated with 08A576071 and 09A583058), entered July 28, 2011, attached hereto as **Exh. 8**; *see also*, Order Denying Product Defendants' Motion in Limine No. 9 to Exclude Testimony, References or Arguments That Challenge the Sufficiency or Adequacy of the Propofol Warnings Federal Law Compelled Product Defendants to Use, *Washington v. Teva Parenteral Medicines, Inc., et al.*, Dist. Ct. Case # A558164, entered September 9, 2011, attached hereto as **Exh. 9**; see also, Order Granting in Part and Denying in Part Product Defendants' Pre-Trial Motion #7 to Admit Evidence and Expert Testimony of the Hatch-Waxman Act, FDA Regulations, Pharmaceutical Industry Practice, and Product Defendants' Compliance Therewith for Propofol, *Washington v. Teva Parenteral Medicines, Inc., et al.*, entered September 20, 2011, attached hereto as **Exh. 10.** Under these circumstances, the doctrine of claim preclusion should serve to estop Defendants from their repeated assertion of these arguments.

Nonetheless, Defendants' motion implies that the entire case at bar should be dismissed because Plaintiffs' Complaint is allegedly an improper effort at shrouding a failure to warn claim that should be preempted by the FDCA as indicated in *PLIVA* cited *supra*, and *Mutual Pharmaceutical, Co., Inc. v. Bartlett*. 570 U.S. 472 (2013). This is simply untrue.

The Complaint does present factual statements and allegations about warnings and knowledge with which Plaintiffs charge the Defendants, but it is in the context of alleging the defective design of the vials Defendants provided to the endoscopy clinic at the heart of this case, i.e., multi-dose vials of propofol which the Defendants and the medical and public health community at large knew subjected patients to infection of blood borne diseases.

It is well established, as recognized by Judge Mahan and Judge Navarro, cited *supra*, that the FDCA does not completely preempt all of a plaintiffs' state law claims, nor does it provide blanket immunity. *In re: Fosamax Products Liab. Litig.*, 965 F.Supp.2d 413, 417-18 (S.D.N.Y. 2013); *Phelps v. Wyeth, Inc., Pliva USA, Inc., et al*., 938 F.Supp.2d 1055, 1061 (D. Or. 2013);

Johnson v. Teva Pharmaceuticals USA, Inc., 2012 WL 1866839, at *3 (W.D. La. May 21, 2012) aff'd, 785 F.3d 605 (5th Cir. 2014). In this regard, Plaintiffs' Complaint pleads narrow and precise strict liability design defect and negligence design claims both of which survive Defendants' federal preemption defense as these allegations do not offend these generic drug manufacturers' duties of sameness or allege that they should have stopped selling propofol.

Allegations of a design defect against a manufacturer of a generic drug which could have only been avoided by altering the active ingredients, route of administration, dosage form, strength or labelling of the brand-name drug, are preempted by the FDCA. *Bartlett*, 570 U.S., at 484. The theory is that because the FDCA requires the generic drug to have the same active ingredients, route of administration, dosage form, strength, and labelling as the brand-name drug on which the generic is based, it is impossible for a generic manufacturer to comply with both federal and state law because it is impossible to lawfully redesign the generic form rendering it different from the brand-name drug to avoid liability; the practice is forbidden under federal law. *Id*. This is called the duty of sameness, a duty to which all generic drug manufacturers are subject. *PLIVA*, 564 U.S., at 613.

Plaintiffs' allegations in the case at bar, however, do not allege Defendants should have acted contra to these federal prohibitions. Rather, the plaintiffs allege that had Defendants simply utilized the FDA-approved design that was available to it and branded manufacturers, i.e., single-dose vials, Plaintiffs would not have suffered the injuries they claim. Plaintiffs stand on the facts and allegations in the operative Complaint to be taken as true, but more specifically, the allegations that the single-dose designed vials were available to them while knowing the risk of not utilizing that design to avoid contamination, are as follows:

- Multiple medical, scientific and public health sources reported whilst Defendants manufactured and sold its generic propofol that infections due to multi-dose vial were reported associated with contamination and patient-to-patient infection, and that the practice of re-using these bottles in clinics was well documented. Complaint, at ¶¶ 20, 22, 23, 24, 28, 34.

- In 2001, Defendants submitted and received FDA-approval for single--dose vials of propofol stating that "a smaller size is safer in the at it may reduce the temptation for dosing multiple patients from a single container thereby reducing opportunities for microbial contamination." Complaint, at ¶ 30.

- Defendants sold its multi-dose vials to the Clinic where Plaintiffs received propofol. ¶ 8.

Selection of the single-dose vial design would not have involved altering the active ingredient in propofol, nor are there any allegations in Plaintiffs' complaint that Defendants should have changed the route of administration, the strength of the drug, or the labelling. Selecting the single-dose design also would not have required defendants to alter the dosage form as prohibited by the FDCA without violating the duty of sameness as the single-dose design was already FDA-approved specifically via an application of one of the defendants at bar.

Plaintiffs have not alleged any fact or claim where avoidance of such would have required Defendants to act in a manner to violate their duties of sameness or require them to stop selling their product[3]. They simply could have elected to utilize the alternative design available to them which would have avoided Plaintiffs' claims. Nevada has adopted the consumer expectation test in determining if a product is defectively designed. *Ford Motor Company v. Trejo*, 133 Nev. 520, 525, 402 P.3d 649, 653 (2017). In the context of proving that a product was defective under the consumer expectation test, an "[a]lternative design is one factor for the jury to consider when evaluating whether a product is unreasonably dangerous." *Ford Motor Company*, 133 Nev. at 525-526 (citing *McCourt v. J.C. Penney Co.,* 103 Nev. 101, 104, P.2d 696, 698 (1987)). Therefore, a plaintiff may choose to support their case with evidence "that a safer alternative design was feasible at the time of manufacture." *Fyssakis v. Knight Equip. Corp.*, 108 Nev. 212, 214, 826 P.2d 570, 572 (1992). Taking all facts and allegations in the complaint as true, this safer alternative was available to Defendants which clears the standard to survive a motion to dismiss for failure to state a claim, i.e., that it is beyond a doubt that Plaintiffs could ever prove facts that would lead to entitlement of relief. *Buzz Stew*,, 124 Nev. at 227–28.

Moreover, even if the Court were to adopt Defendants' interpretation of Plaintiffs' Complaint – that it includes inappropriate failure to warn allegations – dismissal is not warranted at this stage since implied preemption is not an absolute defense if in fact there was another, updated FDA-approved warning or Dear Doctor letter that Defendants failed to adopt or send, which could

[3] *Bartlett* rejected the "stop-selling" rationale put forth by Plaintiffs in that matter stating that in the midst of satisfying both federal and state law obligations, no manufacturer is required to cease acting altogether in order to avoid liability. *Id*., at 570 U.S. at 488. Defendants in the case at bar would not have had to stop selling their product to avoid liability, they simply could have selected the FDA-approved alternative design.

only be determined via discovery. *PLIVA*, 564 U.S. at 613. The duty for a manufacturer of generic drugs is to ensure that its warning label is identical to the label of the brand-name drug and without moving to the discovery phase of this case Plaintiffs would be barred from learning whether the Defendants complied with any such updates. *Id*.

C. DEFENDANTS' VARIOUS CRITICISMS OF PLAINTIFFS' CAUSES OF ACTION ARE UNTENABLE IN LIGHT OF PAST JUDICIAL DECISIONS AND VERDICTS, AND OTHERWISE BARRED BY THE DOCTRINE OF ISSUE PRECLUSION.

A corollary to claim preclusion, issue preclusion is applied to conserve judicial resources, maintain consistency, and avoid harassment or oppression of the adverse party. *Alcantara,* 321 P.3d at 916. For issue preclusion to apply, the following four elements must be met:

> (1) the issue decided in the prior litigation must be identical to the issue presented in the current action;
>
> (2) the initial ruling must have been on the merits and have become final;
>
> (3) the party against whom the judgment is asserted must have been a party or in privity with a party to the prior litigation; and
>
> (4) the issue was actually and necessarily litigated.

Id. See also, Parklane Hosiery Co., Inc.. v. Shore, 439 U.S. 322 (1979), the seminal case approving "offensive" use of collateral estoppel, cited with approval in *Servaites v. Lowden*, 99 Nev. 240, 660 P.2d 1008, 1012 (1983).

In three Endoscopy trials against these Defendants, Judgment was entered on verdicts which specifically found in Plaintiffs' favor on claims of: 1) Strict Liability for Defective Design (*Washington*); 2) Strict Liability for Failure to Warn (*Chanin*); 3) Breach of Implied Warranty of Fitness for a Particular Purpose (*Chanin, Sacks, et al.*); 4) Negligence (*Washington*), 5) Duty to Monitor (*Sacks, et al.*); 6) Failure to Send Dear Doctor Letter (*Sacks, et al.*), and 7) Punitive Damages (*Chanin, Sacks, et al.*, and *Washington*).

On identical facts as will be presented in this case (on the issue of Defendants' liability and amenability to suit), these Defendants have appeared in multiple courts in this jurisdiction, briefed and argued identical legal theories for their absolution, and in each instance those efforts yielded verdicts and judgments against them.

Plaintiffs' burden in the face of the instant Motion to Dismiss is a modest one. Plaintiffs here do not need to prove they will win verdicts against these Defendants. Plaintiffs need not even prove that Defendants' previously-litigated defenses are subject to offensive collateral estoppel – although they arguably are. The point here is simply that the very claims which Defendants assert are legally deficient each passed muster all the way to trial and judgment in three different Clark County courtrooms. Defendants ignore that precedent and provide no basis upon which to disregard or distinguish it, opting instead to once again pursue the same arguments before this Court.

Regrettably, Defendants take their inauthenticity in this endeavor to an extreme. For example, they contend (in the alternative) that Plaintiffs' strict liability claims are "barred by the learned intermediary doctrine". Motion, 15:18-19. The case Defendants cite for this assertion is *Klasch v. Walgreen Co.*, 127 Nev. 832, 264, P.3d 1155, 1158 (2011). However, the *Klasch* opinion makes explicit in **three** separate places that the learned intermediary doctrine is only being adopted "in the context of pharmacist/customer tort litigation". *Id.* at 1157, 1159, 1161 ("Because we believe that these public-policy considerations are sound, we adopt the learned-intermediary doctrine in the context of pharmacist/customer tort litigation").

While it may be that the Nevada Supreme Court would adopt the learned intermediary doctrine more broadly to include drug companies in a different case, *Klasch* is not that case. For Defendants to claim that *Klasch* warrants the dismissal of Plaintiffs' strict products liability claims on learned intermediary grounds is an unjustified stretch. Even at that, *Klasch* sets forth a relevant exception to the doctrine, namely:

> Following the modern trend of case law, we conclude that the learned-intermediary doctrine does not foreclose a pharmacist's potential for liability when the pharmacist has knowledge of a customer-specific risk. Instead, under these circumstances, a pharmacist has a duty to exercise reasonable care in warning the customer or notifying the prescribing doctor of the risk.

Id. at 1158.

Replacing "pharmacist" with "drug company" in the excerpt above, it is clear that these Defendants' superior knowledge of the risk of double-dipping into the larger 50ml bottles of propofol at ambulatory surgical centers, and Defendants' specific knowledge of previous incidents of infection occasioned thereby, likely renders the protections of the learned intermediary doctrine unavailable to them – in similar fashion as the Court found against Walgreens in *Klasch*. In short, the learned intermediary doctrine is not absolute, it requires the teasing out of facts, and Defendants' reliance upon it here is misplaced.

As discussed above, all of Plaintiffs' other claims have previously been allowed to proceed to trial and judgment in this jurisdiction. To the extent there are technical pleading deficiencies that in the Court's view warrant the amending of Plaintiffs' Complaint, Plaintiffs respectfully request leave of Court to cure any arguable deficiencies, as no prejudice to these Defendants would be incurred thereby.

IV. CONCLUSION

For each of the foregoing reasons, Plaintiffs respectfully request that Defendants' Motion to Dismiss be Denied, except as to those Plaintiffs named who are not identified on the Parties' Tolling Agreement (to which the undersigned Counsel would have stipulated had he been asked).

Dated this 3rd day of October, 2019

GLEN LERNER INJURY ATTORNEYS

By:/s/ Glen J. Lerner
Glen J. Lerner, Esq.
Nevada Bar No. 4314
4795 South Durango Drive
Las Vegas, Nevada 89147

WETHERALL GROUP, LTD.
Peter C. Wetherall, Esq.
Nevada Bar No.: 4414
9345 W. Sunset Rd., Ste. 100
Las Vegas, NV 89148
E-mail: pwetherall@wetherallgroup.com
Attorney for Plantiffs

CERTIFICATE OF SERVICE

Pursuant to N.R.C.P. 5(a), E.D.C.R. 7.26(a) and N.E.F.C.R. 9, I hereby certify that I am an employee of GLEN LERNER INJURY ATTORNEYS, and on the 3rd day of October, 2019, the foregoing ***PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS*** was served by electronic means via the Court's Odyssey File & Serve System to the following counsel of record.

PHILIP M. HYMANSON, ESQ.
HENRY JOSEPH HYMANSON, ESQ.
HYMANSON & HYMANSON
8816 Spanish Ridge Avenue
Las Vegas, NV 89148
Co-Counsel for Defendants

ERIC W. SWANIS, ESQ.
JASON K. HICKS, ESQ.
GREENBERG TRAURIG, LLP
10845 Griffith Peak Drive, Suite 600
Las Vegas, Nevada 89135
Co-Counsel for Defendants

/s/ Miriam Alvarez
An employee of Glen Lerner Injury Attorneys

EXHIBIT 1

EXHIBIT 1

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Hepatitis C Investigation in a Las Vegas, Nevada Endoscopy

In January 2008, investigators from CDC's Division of Viral Hepatitis and Division of Health Care Quality Promotion responded to a request from the Southern Nevada Health District (SNHD) to help investigate three persons reported to the local surveillance program with acute Hepatitis C virus (HCV) infection; all three persons had undergone procedures at a Las Vegas endoscopy clinic. Since beginning the investigation, CDC and SNHD have identified a total of six cases of HCV infection among patients who had undergone procedures at the clinic in the 35–90 days prior to onset of symptoms. These patients did not have other risks for HCV infection. Molecular diagnostic testing conducted by CDC confirmed the relatedness of several of these infections.

On investigation of the clinic, CDC and SNHD observed practices that had the potential to transmit HCV. On the basis of these findings, SNHD is notifying 40,000 past patients who were potentially exposed to HCV and other infectious diseases. CDC is providing ongoing support to SNHD for this investigation.

Health care associated transmission of HCV infection accounts for a small proportion of infections in the United States. Since 2001, CDC has identified other HCV outbreaks in health care settings associated with syringe reuse and other lapses in recommended infection control practices.

In response to these investigations, patients with possible exposures associated with these outbreaks were notified and directed to testing for HIV, HBV, and HCV.

For more information about the investigation, visit:

Southern Nevada Health District (http://www.southernnevadahealthdistrict.org/hepc-investigation/index.php)
http://www.southernnevadahealthdistrict.org/outbreaks/index.htm
If you have additional concerns, you may contact the Southern Nevada Health District at 702-759-INFO (4636).

Information about viral hepatitis, HIV, and syringe safety are available on the CDC website at:

Viral Hepatitis
http://www.cdc.gov/hepatitis

HIV Questions and Answers (Q&A)
http://www.cdc.gov/hiv/basics/index.html

A Patient Safety Threat – Syringe Reuse
Division of Health Care Quality Promotion, February 2008

Quick Links to Hepatitis ...
A | B | C | D | E

APP1098

Viral Hepatitis Home

Statistics & Surveillance

Populations & Settings

Outbreaks

State and Local Partners & Grantees

Policy and Programs

Resource Center

Page last reviewed: May 31, 2015

Page last updated: May 31, 2015

Content source: Division of Viral Hepatitis (/hepatitis) and

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (/nchhstp)

EXHIBIT 2

EXHIBIT 2

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

* * *

A-18-782023-C

MAUREEN BRIDGES, *et al.*,

Plaintiffs,

v.

TEVA PARENTERAL MEDICINES, INC., *et al.*,

Defendants.

Case No. 2:18-cv-02310-JCM-VCF

ORDER

Presently before the court is individual plaintiffs' motion to remand. (ECF No. 9). Defendants Baxter Healthcare Corporation; McKesson Medical-Surgical Inc.; Sicor, Inc.; and Teva Parenteral Medicines, Inc. (collectively "defendants") responded (ECF No. 11), to which plaintiffs replied (ECF No. 12).

Also before the court is defendants' motion for leave to file surreply. (ECF No. 14).

I. Facts

The plaintiffs in this action are individuals that received medical care at the Endoscopy Center ("clinic") located at 700 Shadow Land, Clark County, Nevada. (ECF No. 1). Defendants supplied the clinic with medical products that the clinic would use in providing various anesthesia services. *Id.* The clinic improperly administered defendants' medical products by re-using injection syringes and anesthesia bottles, which created a foreseeable risk of infection or cross-contamination. *Id.*

On or about February 28, 2008, the Southern Nevada Health District sent plaintiffs and approximately 60,000 others a letter informing them that the clinic placed them at a risk of possible exposure to bloodborne pathogens. *Id.* The Health District recommended that

plaintiffs' get tested for hepatitis C, hepatitis B, and HIV. *Id.* Plaintiffs followed the Health District's recommendation and eventually discovered that they did not contract any of the aforementioned diseases. *Id.*

Plaintiffs believe that defendants' improper packaging of their medical products caused the clinic to improperly re-use syringes and bottles. *Id.* On April 11, 2016, plaintiffs offered to settle their claims in exchange for $4,252,500, which amounts to $2,500 per plaintiff. (ECF No. 9). Defendants rejected plaintiffs' offer. *Id.*

On October 1, 2018, plaintiffs initiated this action in state court, asserting four causes of action: (1) strict product liability; (2) breach of the implied warranty of fitness for a particular purpose; (3) negligence; and (4) violation of the Nevada Deceptive Trade Practices Act. (ECF No. 1).

On December 10, 2018, defendants removed this action to federal court. *Id.* The court now determines whether it has subject matter jurisdiction.

II. Legal Standard

Pursuant to 28 U.S.C. § 1441(a), "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending." 28 U.S.C. § 1441(a). "A federal court is presumed to lack jurisdiction in a particular case unless the contrary affirmatively appears." *Stock West, Inc. v. Confederated Tribes of Colville Reservation*, 873 F.2d 1221, 1225 (9th Cir. 1989).

Upon notice of removability, a defendant has thirty days to remove a case to federal court once he knows or should have known that the case was removable. *Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1250 (9th Cir. 2006) (citing 28 U.S.C. § 1446(b)(2)). Defendants are not charged with notice of removability "until they've received a paper that gives them enough information to remove." *Id.* at 1251.

Specifically, "the 'thirty-day time period [for removal] . . . starts to run from defendant's receipt of the initial pleading only when that pleading affirmatively reveals on its face' the facts necessary for federal court jurisdiction." *Id.* at 1250 (quoting *Harris v. Bankers Life & Casualty*

Co., 425 F.3d 689, 690–91 (9th Cir. 2005) (alterations in original)). "Otherwise, the thirty-day clock doesn't begin ticking until a defendant receives 'a copy of an amended pleading, motion, order or other paper' from which it can determine that the case is removable. *Id.* (quoting 28 U.S.C. § 1446(b)(3)).

A plaintiff may challenge removal by timely filing a motion to remand. 28 U.S.C. § 1447(c). On a motion to remand, the removing defendant faces a strong presumption against removal, and bears the burden of establishing that removal is proper. *Sanchez v. Monumental Life Ins. Co.*, 102 F.3d 398, 403–04 (9th Cir. 1996); *Gaus v. Miles, Inc.*, 980 F.2d 564, 566–67 (9th Cir. 1992).

III. Discussion

As a preliminary matter, the court notes that plaintiffs have filed a surreply in opposition to defendants' motion to remand (ECF No. 13) and defendants now move for leave to file their own surreply (ECF No. 14). Because the filings pertain to legal authority that is not binding on this court and "motions for leave to file a surreply are discouraged[,]" the court will strike plaintiffs surreply (ECF No. 13) and deny defendants' motion (ECF No. 14). LR 7-2(b).

Plaintiffs move to remand, arguing that the court does not have diversity jurisdiction. (ECF No. 9). Defendants' contend that the court has both diversity and federal question jurisdiction. (ECF No. 11). The court will address both of defendants' purported grounds for subject matter jurisdiction in turn.

a. Diversity jurisdiction

28 U.S.C. § 1332 allows federal courts to exercise diversity jurisdiction in civil actions between citizens of different states where the amount in controversy exceeds $75,000. *See* 28 U.S.C. § 1332(a). "In determining the amount in controversy, courts first look to the complaint. Generally, 'the sum claimed by the plaintiff controls if the claim is apparently made in good faith.'" *Ibarra v. Manheim Invests., Inc.* 775 F.3d 1193, 1197 (9th Cir. 2015) (citing *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 289 (1938)). At the time of removal, parties may submit supplemental evidence to show that the amount in controversy is in excess of $75,000. *Id.* (citing *Singer v. State Farm Mut. Auto. Ins. Co.*, 116 F.3d 373, 377 (9th Cir. 1997).

Plaintiffs allege in the complaint that their claims are each valued in excess of $15,000 in general damages. (ECF No. 1). This figure is well below the amount in controversy threshold under § 1332(a) and defendants have not submitted any evidence showing that a greater amount is in dispute.

Nevertheless, defendants contend that the amount in controversy is in excess of $75,000 because plaintiffs also seek attorney's fees and punitive damages. (ECF No. 11). The court now must determine whether defendants have proven by a preponderance of the evidence that punitive damages and attorney's fees, coupled with general damages, will exceed the jurisdiction minimum. *See Sanchez v. Monumental Life Ins. Co.*, 102 F.3d 398, 403-04 (9th Cir. 1996).

i. Punitive damages

Courts consider punitive damages in determining the amount in controversy when a plaintiff can recover punitive damages as a matter of law. *Gibson v. Chrysler Corp.*, 261 F.3d 927, 945 (9th Cir. 2001). Under Nevada law, a plaintiff can recover punitive damages only by proving with clear and convincing evidence that the defendant is guilty of oppression, fraud, or malice. Nev. Rev. Stat. 42.005(1). In light of NRS 42.005, the court will consider punitive damages for jurisdictional purposes.

Courts generally look to jury awards in analogous cases in determining how to consider punitive damages towards satisfying the jurisdictional minimum. *See Campbell v. Hartford Life Ins. Co.*, 825 F. Supp. 2d 1005, 1008 (E.D. Cal. 2011). Here, defendants have not provided any factual support, other than citing statutes, pertaining to the probable amount of punitive damages. Therefore, defendants have not shown by a "preponderance of the evidence" that punitive damages increase the amount in controversy. *See Sanchez*, 102 F.3d at 404.

ii. Attorney's fees

Courts consider attorney's fees in determining the amount in controversy if a plaintiff can recover such fees pursuant to a contract or statute. *Galt G/S v. JSS Scandinavia*, 142 F.3d 1150, 1156 (9th Cir. 1998). Nevada law allows courts to award attorney's fees when (1) the prevailing party has not recovered more than $20,000 or (2) when the opposing party's defense was "brought or maintained without reasonable grounds or to harass the prevailing party." Nev. Rev.

Stat. 18.010(2). Because each plaintiff appears to seek less than $20,000 in damages, the court will consider attorney's fees in determining the amount in controversy.

Defendants' argue that attorney's fees will spike the cost of this action because this case involves hundreds of plaintiffs. (ECF No. 11). The complex nature of this lawsuit compels the court to conclude that plaintiffs will incur significant attorney's fees. However, defendants' once again have not provided evidence showing the extent that attorney's fees increase the amount in controversy. Indeed, the court does not find that attorney's fees would quadruple or quintuple the ultimate award.

In sum, defendants have not shown by a preponderance of the evidence an amount in controversy in excess of $75,000. Accordingly, the court cannot exercise subject matter jurisdiction under § 1332(a).

b. Federal question jurisdiction

The "well-pleaded complaint rule" governs federal question jurisdiction. This rule provides that district courts can exercise jurisdiction under 28 U.S.C. § 1331 only when a federal question appears on the face of a well-pleaded complaint. *See, e.g.*, *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). Thus, a plaintiff "may avoid federal jurisdiction by exclusive reliance on state law." *Id.* Moreover, "an anticipated or actual federal defense generally does not qualify a case for removal[.]" *Jefferson County v. Acker*, 527 U.S. 423, 431 (1999).

The well-pleaded complaint rule does not require a plaintiff to assert a federal cause of action. District court also have jurisdiction over state law claims that raise "some substantial, disputed question of federal law[.]" *Indep. Living Ctr. of Southern California, Inc. v. Kent*, 909 F.3d 272, 279 (9th Cir. 2018). Indeed, federal question jurisdiction exists when a federal issue is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disturbing the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

Defendants argue that plaintiffs' state tort claims, which allege that defendants improperly packaged medical products, raise a substantial issue of federal law because the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, governs the

packaging of medical products. (ECF No. 11). The court disagrees.

In *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, the Supreme Court held that state law claims which allege violations of the FDCA do not raise a substantial federal question because Congress did not intend to create a private right of action for violation of the FDCA. *Wander v. Kaus*, 304 F.3d 856, 859 (9th Cir. 2002) (citing *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 808 (1986)). As the circumstances of this case fall well within *Merrell Dow*, the court concludes that plaintiffs' complaint does not raise a substantial federal question.

The court notes that defendants' arguments are unclear, incoherent, and at times confused. Some paragraphs from defendants' brief appear to assert that the court has jurisdiction because the FDCA preempts plaintiffs' state law claims. To ensure complete adjudication of all pertinent issues that the parties raise, the court will consider this argument.

The "complete preemption doctrine" allows district courts to exercise federal question jurisdiction over state law claims when a federal statute completely preempts the relevant state law. *Balcorta v. Twentieth Century-Fox Film Corp.*, 208 F.3d 1102, 1107 (9th Cir. 2000) (citation omitted). Courts consider the factual allegations in the complaint and the petition of removal to determine whether federal law completely preempts a state law claim. *Schroeder v. Trans World Airlines, Inc.*, 702 F.2d 189, 191 (9th Cir. 1983).

It is well established that the FDCA does not completely preempt state law. *See Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1259–60 (D. Or. 2011); *see also Perez v. Nidek Co. Ltd.*, 657 F. Supp. 2d 1156, 1161 (S.D. Cal. 2009); *see also Alaska v. Eli Lilly & Co.*, No. 3:06-cv-88 TMB, 2006 WL 2168831 at *3–4 (D. Ala July 28, 2006). Therefore, the court does not have federal question jurisdiction under the complete preemption doctrine.

IV. Conclusion

The court does not have subject matter jurisdiction because the amount in controversy is not in excess of $75,000, plaintiffs' complaint does not raise a substantial federal question, and the FDCA does not completely preempt plaintiffs' state law claims.

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Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that plaintiffs' motion to remand (ECF No. 9) be, and the same hereby is, GRANTED.

IT IS FURTHER ORDERED that defendants' motion for leave to file surreply (ECF No. 14) be, and the same hereby is, DENIED, consistent with the foregoing.

IT IS FURTHER ORDERED that defendants' motion to dismiss (ECF No. 3) be, and the same hereby is, DENIED without prejudice.

IT IS FURTHER ORDERED that the matter of *Bridges et al. v. Teva Parenteral Medicines, Inc. et al.*, case number 2:18-cv-02310-JCM-VCF, be, and the same hereby is, REMANDED.

The clerk shall strike plaintiffs' surreply (ECF No. 13) and close the case accordingly.

DATED THIS 12th day of April 2019.

James C. Mahan

JAMES C. MAHAN
UNITED STATES DISTRICT JUDGE

I hereby attest and certify on 4/12/2019 that the foregoing document is a full, true and correct copy of the original on file in my legal custody.

CLERK, U.S. DISTRICT COURT
DISTRICT OF NEVADA

By MONICA REYES Deputy Clerk

I hereby attest and certify on _____
that the foregoing document is a full, true
and correct copy of the original on file in my
legal custody.

CLERK, U.S. DISTRICT COURT
DISTRICT OF NEVADA

By_____ Deputy Clerk

CLOSED

United States District Court
District of Nevada (Las Vegas)
CIVIL DOCKET FOR CASE #: 2:18-cv-02310-JCM-VCF

Bridges et al v. Teva Parenteral Medicines, Inc. et al
Assigned to: Judge James C. Mahan
Referred to: Magistrate Judge Cam Ferenbach
Case in other court: Eighth Judicial District Court, Clark County, NV, A-18-782023-C
Cause: 28:1441 Petition for Removal- Product Liability

Date Filed: 12/05/2018
Date Terminated: 04/12/2019
Jury Demand: None
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical Personal Injury Product Liability
Jurisdiction: Diversity

Plaintiff

Maureen Bridges

represented by **Peter C Wetherall**
Wetherall Group, Ltd.
9345 W. Sunset Road
Suite 100
Las Vegas, NV 89148
702-838-8500
Fax: 702-837-5081
Email: pwetherall@wetherallgroup.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Maria Liss

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Mary Cattledge

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Franklin Corpuz

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Barbara Eddowes

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Arthur Einhorn

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Carol Einhorn

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ATTORNEY TO BE NOTICED

Plaintiff

Anne Hayes represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Homero Hernandez represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sophie Hinchliff represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Angel Barahona represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Marta Fernandez–Ventura represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

William Fraley represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Richard Francis represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Georgina Hetherington represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Janice Hoffman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

George Johnson represented by **Peter C Wetherall**
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Linda Johnson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sheron Johnson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Steve Johnson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sean Keenan represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Karen Keeney represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Diane Kircher represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Orville Kircher represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Stephanie Kline represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Kimberly Kunkle represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Patricia Lewis-Glynn represented by

Peter C Wetherall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Bette Long represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Peter Longly represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Diana Lousignont represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Maria Kollender represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

David Magee represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Francisco Mantua represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Dana Martin represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Maria Martinez represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

John Mauizio represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Anga McClain
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Barry McGiffin
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Marian Miller
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Hiep Moraga
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Sondra Moreno
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Jimmy Nix
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Nancy Norman
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Georgia Olson
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Mark Olson
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Beverly Perkins
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Maryjane Perry represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Ricky Peterson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Brandilla Pross represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Dallas Pymm represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Leeann Pinson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Shirley Pyrtle represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Evonne Quast represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Ronald Quast represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Leanne Robie represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Eleanor Rowe represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Plaintiff

Ronald Rowe represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Delores Russ represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Massimino Russello represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Geolene Schaller represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Jan Michael Shultz represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Francine Siegel represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Marlene Siems represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Ratanakorn Skelton represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Wallace Stevenson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Robert Stewart represented by **Peter C Wetherall**
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Rory Sundstrom represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Carol Swan represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sony Syamala represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Richard Tafaya represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Jacqueline Beattie represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Prentice Besore represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Irene Bilski represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Viola Brottlund-Wagner represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Patrick Christopher represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Paul Denorio represented by

Peter C Wetherall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

David Donner represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Timothy Dyer represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Demecio Giron represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Carol Hiel represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Carolyn Lamyer represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Rebecca Lerma represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Julie Kalsnes represented by **Peter C Wetherall**
formerly known as (See above for address)
Olson *LEAD ATTORNEY*
ATTORNEY TO BE NOTICED

Plaintiff

Fanny Poor represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Franco Provinciali represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Joellen Shelton represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Frank Stein represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Janet Stein represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Lois Thompson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Frank Torres represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Frank Beall represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Peter Billitteri represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Irene Cal represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Cindy Cook represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Evelyn Ealy represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Kristen Foster
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Phillip Garcia
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
June Johnson
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Larry Johnson
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
William Kepner
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Peggy Legg
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Jose Lozano
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Josephine Lozano
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Deborah Madison
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Michael Malone
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Plaintiff

Ann Marie Morales

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Gina Russo

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Colleen Tranquill

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Loraine Turrell

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Graham Tye

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Scott Vandermolin

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Louise Verdel

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

J. Holland Wallis

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Angela Hamler
formerly known as
Washington

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sharon Wilkins

represented by **Peter C Wetherall**
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Mark Williamson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Steve Willis represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Benyam Yohannes represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Michal Zookin represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Lidia Aldanay represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Maridee Alexander represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Elsie Ayers represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Jack Ayers represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Catherine Barber represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Levelyn Barber represented by

Peter C Wetherall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Matthew Beauchamp represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sedra Beckman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Thomas Beem represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Emma Ruth Bell represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Nathania Bell represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Pamela Bertrand represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Vicki Beverly represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Fred Blackington represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Barbara Blair represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Michelle Boyce
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Noranne Brumagan
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Howard Bugher
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Robert Buster
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Winifred Carter
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Codell Chavis
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Bonnie Clark
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Kip Cooper
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Michel Cooper
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Christa Coyne
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Nikki Dawson
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Lou Decker
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Peter Dempsey
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Maria Dominguez
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Carolyn Donahue
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Lawrence Donahue
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Conrad Dupont
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Deborah Esteen
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Lupe Evangelist
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Karen Fanelli
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Plaintiff

LaFonda Flores represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Madeline Foster represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Eloise Freeman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Ellamae Gaines represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Leah Girma represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Antonio Gonzales represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Francisco Gonzales represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Richard Green represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Isabel Grijalva represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

James Hamilton represented by **Peter C Wetherall**
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Brenda Harman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Donald Harman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Susan Henning represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Jose Hernandez represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Marie Hoeg represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
James H. McAvoy represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Marguarite M. McAvoy represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
William DeHaven represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Veloy E. Burton represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Shirley Carr represented by

Peter C Wetherall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Mary Dominguez represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Camille Howey represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Lavada Shipers represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Jannie Smith represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Mildred J. Tweedy represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Salvatore J. Sberna represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Joseph Perrelli represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Joseph Lewandowski represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Carole Lee Perrelli represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Muriel Carol Hinman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Kenneth D. Hinman represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Janice Welsh represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Lola Hall represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

James Gum
also known as
"Dick" represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Audrey Gum represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Patrick Snyder represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Nancy Titmuss represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Michael Titmuss represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Phyllis J. Bodell represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Helen Hackett
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Martha Turner
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Robert Rugg
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Katherine Holzhauer
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Alicia Hoskinson
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Greg Houck
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
John Julian
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
William Kader
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Mary Ellen Kaiser
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Vasiliki Kalkantzakos
represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Plaintiff

William Keeler represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Robert Kellar represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Shirley Kellar represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Melanie Keppel represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Anita Kinchen represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Peter Klas represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Linda Kobige represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Linda Korschinowski represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Durango Lane represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

June Langer represented by **Peter C Wetherall**
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Dionne Jenkins represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Nancy Lapa represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Edward Levine represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Mersey Lindsey represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Zolman Little represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Steve Lyons represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Marsene Maksymowski represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Pat Marino represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Billie Mathews represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Kristine Mayeda represented by

Peter C Wetherall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Carmen McCall represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Michael McCoy represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Annette Medland represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Josephine Molina represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Len Monaco represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Rachel Montoya represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Theodore Morrison represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Xuan Mai Ngo represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Jacqueline Novak represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Faith O'Brien represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Javier Pacheco represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Eli Pinsonault represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Florence Pinsonault represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Steve Pokres represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Timothy Price represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Steven Rausch represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Denise Orr represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Clifton Rollins represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
John Romero represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Jean Rose

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Ronald Ruther

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Juan Salazar

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Priscilla Saldana

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Buddie Salsbury

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Bernice Sanders

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Carl Smith

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Danny Scalice

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Vickie Smith

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

William Snedeker

represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Plaintiff

Edward Solis represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Mary Soliz represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Roger Sowinski represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Cynthia Spencer represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Stephen Stagg represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Troy Staten represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Linda Steiner represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Gwen Stone represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Phaedra Sunday represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Edward Suter represented by **Peter C Wetherall**
(See above for address)

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Clarence Taylor represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Catherine Thompson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Margrett Thompson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Vernon Thompson represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
David Tomlin represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Von Trimble represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Chuong Van Trong represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
John Viccia represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Steven Vig represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Janet Vopinek represented by

Peter C Wetherall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Kathy Walent represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Linda Walker represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Shirley Washington represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Mary Wentworth represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Betty Werner represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Sally West represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Dee Louise Whitney represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Shirley Woods represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Tony Yutyatat represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Catalina Zafra represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Metro Zamito represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Christina Zepeda represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Andrew Zielinski represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Carolyn Armstrong represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Betty Bradley represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Charleen Davis–Shaw represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Rebecca Day represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Dion Draugh represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff
Vincenzo Esposito represented by **Peter C Wetherall**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

V.

Defendant

Teva Parenteral Medicines, Inc.
formerly known as
Sicor Pharmaceuticals, Inc.

represented by **Philip M Hymanson**
Hymanson and Hymanson
8816 Spanish Ridge Ave
Las Vegas, NV 89148
702-629-3300
Fax: 702-629-3332
Email: Phil@HymansonLawNV.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Henry Joseph Hymanson
Hymanson and Hymanson
8816 Spanish Ridge Ave
Las Vegas, NV 89148
702-629-3300
Fax: 702-629-3332
Email: Hank@HymansonLawNV.com
ATTORNEY TO BE NOTICED

Defendant

Sicor, Inc.

represented by **Philip M Hymanson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Henry Joseph Hymanson
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

Baxter Healthcare Corporation

represented by **Philip M Hymanson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Henry Joseph Hymanson
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

McKesson Medical-Surgical Inc.

represented by **Philip M Hymanson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Henry Joseph Hymanson
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
12/10/2018	1	PETITION FOR REMOVAL from Eighth Judicial District Court, Clark County, Nevada, Case Number A-18-782023-C, (Filing fee $ 400 receipt number 0978-5353020) by Baxter Healthcare Corporation, McKesson Medical-Surgical Inc., Sicor, Inc., and Teva Parenteral Medicines, Inc. Proof of service due by 12/30/2018. (Attachments: # 1 Civil Cover Sheet)(Hymanson, Philip)

		NOTICE of Certificate of Interested Parties requirement: Under Local Rule 7.1−1, a party must immediately file its disclosure statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court. Modified to include all filers on 12/10/2018 (EDS). (Entered: 12/10/2018)
12/10/2018		Case assigned to Judge James C. Mahan and Magistrate Judge Cam Ferenbach. (MR) (Entered: 12/10/2018)
12/10/2018	2	MINUTE ORDER IN CHAMBERS of the Honorable Judge James C. Mahan on 12/10/2018. Statement regarding removed action is due by 12/25/2018. Joint Status Report regarding removed action is due by 1/9/2019. (Copies have been distributed pursuant to the NEF − MR) (Entered: 12/10/2018)
12/17/2018	3	MOTION to Dismiss by Defendants Baxter Healthcare Corporation, McKesson Medical−Surgical Inc., Sicor, Inc., Teva Parenteral Medicines, Inc.. Responses due by 12/31/2018. (Attachments: # 1 Exhibit Index and Exhibits A through N) (Hymanson, Philip) (Entered: 12/17/2018)
12/20/2018	4	CERTIFICATE of Interested Parties by Baxter Healthcare Corporation, McKesson Medical−Surgical Inc., Sicor, Inc., Teva Parenteral Medicines, Inc. that identifies all parties that have an interest in the outcome of this case. Corporate Parent Teva Pharmaceutical Industries Ltd., Corporate Parent Sicor, Inc., Corporate Parent Teva Pharmaceuticals USA, Inc., Corporate Parent Orvet UK, Corporate Parent Teva Pharmaceuticals Europe B.V., Corporate Parent Teva Pharmaceutical Holdings Cooperatieve U.A., Corporate Parent IVAX LLC for Teva Parenteral Medicines, Inc.; Corporate Parent McKesson Corporation for McKesson Medical−Surgical Inc.; Corporate Parent Teva Pharmaceutical Industries Ltd., Corporate Parent Teva Pharmaceuticals USA, Inc., Corporate Parent Orvet UK, Corporate Parent Teva Pharmaceuticals Europe B.V., Corporate Parent Teva Pharmaceutical Holdings Cooperatieve U.A., Corporate Parent IVAX LLC for Sicor, Inc.; Corporate Parent Baxter International, Inc. for Baxter Healthcare Corporation added. (Hymanson, Philip) (Entered: 12/20/2018)
12/23/2018	5	CERTIFICATE of Interested Parties by Lidia Aldanay, Maridee Alexander, Carolyn Armstrong, Elsie Ayers, Jack Ayers, Angel Barahona, Catherine Barber, Levelyn Barber, Frank Beall, Jacqueline Beattie, Matthew Beauchamp, Sedra Beckman, Thomas Beem, Emma Ruth Bell, Nathania Bell, Pamela Bertrand, Prentice Besore, Vicki Beverly, Peter Billitteri, Irene Bilski, Fred Blackington, Barbara Blair, Phyllis J. Bodell, Michelle Boyce, Betty Bradley, Maureen Bridges, Viola Brottlund−Wagner, Noranne Brumagan, Howard Bugher, Veloy E. Burton, Robert Buster, Irene Cal, Shirley Carr, Winifred Carter, Mary Cattledge, Codell Chavis, Patrick Christopher, Bonnie Clark, Cindy Cook, Kip Cooper, Michel Cooper, Franklin Corpuz, Christa Coyne, Charleen Davis−Shaw, Nikki Dawson, Rebecca Day, William DeHaven, Lou Decker, Peter Dempsey, Paul Denorio, Maria Dominguez, Mary Dominguez, Carolyn Donahue, Lawrence Donahue, David Donner, Dion Draugh, Conrad Dupont, Timothy Dyer, Evelyn Ealy, Barbara Eddowes, Arthur Einhorn, Carol Einhorn, Vincenzo Esposito, Deborah Esteen, Lupe Evangelist, Karen Fanelli, Marta Fernandez−Ventura, Woodrow Finney, LaFonda Flores, Kristen Foster, Madeline Foster, William Fraley, Richard Francis, Eloise Freeman, Joan Frenken, Emma Fuentes, Ellamae Gaines, Phillip Garcia, Judith Gerences, Annie Gillespie, Leah Girma, Demecio Giron, Antonio Gonzales, Francisco Gonzales, Richard Green, Cynthia Griem−Rodriguez, Isabel Grijalva, Audrey Gum, James Gum, Helen Hackett, Debbie Hall, Lloyd Hall, Lola Hall, Shanera Hall, Virginia Hall, James Hamilton, Angela Hamler, Brenda Harman, Donald Harman, Anne Hayes, Susan Henning, Homero Hernandez, Jose Hernandez, Georgina Hetherington, Carol Hiel, Sophie Hinchliff, Kenneth D. Hinman, Muriel Carol Hinman, Marie Hoeg, Janice Hoffman, Katherine Holzhauer, Alicia Hoskinson, Greg Houck, Camille Howey, Dionne Jenkins, George Johnson, June Johnson, Larry Johnson, Linda Johnson, Sheron Johnson, Steve Johnson, John Julian, William Kader, Mary Ellen Kaiser, Vasiliki Kalkantzakos, Julie Kalsnes, William Keeler, Sean Keenan, Karen Keeney, Robert Kellar, Shirley Kellar, William Kepner, Melanie Keppel, Anita Kinchen, Diane Kircher, Orville Kircher, Peter Klas, Stephanie Kline, Linda Kobige, Maria Kollender, Linda Korschinowski, Kimberly Kunkle, Carolyn Lamyer, Durango Lane, June Langer, Nancy Lapa, Peggy Legg, Rebecca Lerma, Edward Levine, Joseph Lewandowski, Patricia Lewis−Glynn, Mersey Lindsey, Maria Liss, Zolman Little, Bette Long, Peter Longly, Diana Lousignont, Jose Lozano, Josephine Lozano, Steve Lyons, Deborah Madison, David Magee, Marsene

		Maksymowski, Michael Malone, Francisco Mantua, Pat Marino, Dana Martin, Maria Martinez, Billie Mathews, John Mauizio, Kristine Mayeda, James H. McAvoy, Marguarite M. McAvoy, Carmen McCall, Anga McClain, Michael McCoy, Barry McGiffin, Annette Medland, Marian Miller, Josephine Molina, Len Monaco, Rachel Montoya, Hiep Moraga, Ann Marie Morales, Sondra Moreno, Theodore Morrison, Xuan Mai Ngo, Jimmy Nix, Nancy Norman, Jacqueline Novak, Faith O'Brien, Georgia Olson, Mark Olson, Denise Orr, Javier Pacheco, Beverly Perkins, Carole Lee Perrelli, Joseph Perrelli, Maryjane Perry, Ricky Peterson, Leeann Pinson, Eli Pinsonault, Florence Pinsonault, Steve Pokres, Fanny Poor, Timothy Price, Brandilla Pross, Franco Provinciali, Dallas Pymm, Shirley Pyrtle, Evonne Quast, Ronald Quast, Steven Rausch, Leanne Robie, Clifton Rollins, John Romero, Jean Rose, Eleanor Rowe, Ronald Rowe, Robert Rugg, Delores Russ, Massimino Russello, Gina Russo, Ronald Ruther, Juan Salazar, Priscilla Saldana, Buddie Salsbury, Bernice Sanders, Salvatore J. Sberna, Danny Scalice, Geolene Schaller, Joellen Shelton, Lavada Shipers, Jan Michael Shultz, Francine Siegel, Marlene Siems, Ratanakorn Skelton, Carl Smith, Jannie Smith, Vickie Smith, William Snedeker, Patrick Snyder, Edward Solis, Mary Soliz, Roger Sowinski, Cynthia Spencer, Stephen Stagg, Troy Staten, Frank Stein, Janet Stein, Linda Steiner, Wallace Stevenson, Robert Stewart, Gwen Stone, Phaedra Sunday, Rory Sundstrom, Edward Suter, Carol Swan, Sony Syamala, Richard Tafaya, Clarence Taylor, Catherine Thompson, Lois Thompson, Margrett Thompson, Vernon Thompson, Michael Titmuss, Nancy Titmuss, David Tomlin, Frank Torres, Colleen Tranquill, Von Trimble, Chuong Van Trong, Martha Turner, Loraine Turrell, Mildred J. Tweedy, Graham Tye, Scott Vandermolin, Louise Verdel, John Viccia, Steven Vig, Janet Vopinek, Kathy Walent, Linda Walker, J. Holland Wallis, Shirley Washington, Janice Welsh, Mary Wentworth, Betty Werner, Sally West, Dee Louise Whitney, Sharon Wilkins, Mark Williamson, Steve Willis, Shirley Woods, Benyam Yohannes, Tony Yutyatat, Catalina Zafra, Metro Zamito, Christina Zepeda, Andrew Zielinski, Michal Zookin. There are no known interested parties other than those participating in the case (Wetherall, Peter) (Entered: 12/23/2018)
12/26/2018	6	STATEMENT REGARDING REMOVAL by Defendants Baxter Healthcare Corporation, McKesson Medical-Surgical Inc., Sicor, Inc., Teva Parenteral Medicines, Inc.. (Hymanson, Philip) (Entered: 12/26/2018)
12/31/2018	7	STIPULATION FOR EXTENSION OF TIME (First Request) TO CONTINUE (First Request) re 3 Motion to Dismiss, by Plaintiffs Lidia Aldanay, Maridee Alexander, Carolyn Armstrong, Elsie Ayers, Jack Ayers, Angel Barahona, Catherine Barber, Levelyn Barber, Frank Beall, Jacqueline Beattie, Matthew Beauchamp, Sedra Beckman, Thomas Beem, Emma Ruth Bell, Nathania Bell, Pamela Bertrand, Prentice Besore, Vicki Beverly, Peter Billitteri, Irene Bilski, Fred Blackington, Barbara Blair, Phyllis J. Bodell, Michelle Boyce, Betty Bradley, Maureen Bridges, Viola Brottlund-Wagner, Noranne Brumagan, Howard Bugher, Veloy E. Burton, Robert Buster, Irene Cal, Shirley Carr, Winifred Carter, Mary Cattledge, Codell Chavis, Patrick Christopher, Bonnie Clark, Cindy Cook, Kip Cooper, Michel Cooper, Franklin Corpuz, Christa Coyne, Charleen Davis-Shaw, Nikki Dawson, Rebecca Day, William DeHaven, Lou Decker, Peter Dempsey, Paul Denorio, Maria Dominguez, Mary Dominguez, Carolyn Donahue, Lawrence Donahue, David Donner, Dion Draugh, Conrad Dupont, Timothy Dyer, Evelyn Ealy, Barbara Eddowes, Arthur Einhorn, Carol Einhorn, Vincenzo Esposito, Deborah Esteen, Lupe Evangelist, Karen Fanelli, Marta Fernandez-Ventura, Woodrow Finney, LaFonda Flores, Kristen Foster, Madeline Foster, William Fraley, Richard Francis, Eloise Freeman, Joan Frenken, Emma Fuentes, Ellamae Gaines, Phillip Garcia, Judith Gerences, Annie Gillespie, Leah Girma, Demecio Giron, Antonio Gonzales, Francisco Gonzales, Richard Green, Cynthia Griem-Rodriguez, Isabel Grijalva, Audrey Gum, James Gum, Helen Hackett, Debbie Hall, Lloyd Hall, Lola Hall, Shanera Hall, Virginia Hall, James Hamilton, Angela Hamler, Brenda Harman, Donald Harman, Anne Hayes, Susan Henning, Homero Hernandez, Jose Hernandez, Georgina Hetherington, Carol Hiel, Sophie Hinchliff, Kenneth D. Hinman, Muriel Carol Hinman, Marie Hoeg, Janice Hoffman, Katherine Holzhauer, Alicia Hoskinson, Greg Houck, Camille Howey, Dionne Jenkins, George Johnson, June Johnson, Larry Johnson, Linda Johnson, Sheron Johnson, Steve Johnson, John Julian, William Kader, Mary Ellen Kaiser, Vasiliki Kalkantzakos, Julie Kalsnes, William Keeler, Sean Keenan, Karen Keeney, Robert Kellar, Shirley Kellar, William Kepner, Melanie Keppel, Anita Kinchen, Diane Kircher, Orville Kircher, Peter Klas, Stephanie Kline, Linda Kobige, Maria Kollender, Linda Korschinowski, Kimberly Kunkle, Carolyn Lamyer, Durango Lane, June

		Langer, Nancy Lapa, Peggy Legg, Rebecca Lerma, Edward Levine, Joseph Lewandowski, Patricia Lewis-Glynn, Mersey Lindsey, Maria Liss, Zolman Little, Bette Long, Peter Longly, Diana Lousignont, Jose Lozano, Josephine Lozano, Steve Lyons, Deborah Madison, David Magee, Marsene Maksymowski, Michael Malone, Francisco Mantua, Pat Marino, Dana Martin, Maria Martinez, Billie Mathews, John Mauizio, Kristine Mayeda, James H. McAvoy, Marguarite M. McAvoy, Carmen McCall, Anga McClain, Michael McCoy, Barry McGiffin, Annette Medland, Marian Miller, Josephine Molina, Len Monaco, Rachel Montoya, Hiep Moraga, Ann Marie Morales, Sondra Moreno, Theodore Morrison, Xuan Mai Ngo, Jimmy Nix, Nancy Norman, Jacqueline Novak, Faith O'Brien, Georgia Olson, Mark Olson, Denise Orr, Javier Pacheco, Beverly Perkins, Carole Lee Perrelli, Joseph Perrelli, Maryjane Perry, Ricky Peterson, Leeann Pinson, Eli Pinsonault, Florence Pinsonault, Steve Pokres, Patty Post, Timothy Price, Brandilla Pross, Franco Provinciali, Dallas Pymm, Shirley Pyrtle, Bonnie Quast, Ronald Quast, Steven Rausch, Leanne Robie, Clifton Rollins, John Romero, Jean Rose, Eleanor Rowe, Ronald Rowe, Robert Rugg, Delores Russ, Massimino Russello, Gina Russo, Ronald Ruther, Juan Salazar, Priscilla Saldana, Buddie Salsbury, Bernice Sanders, Salvatore J. Sberna, Danny Scalice, Geolene Schaffer, Joellen Shelton, Lavada Shipers, Jan Michael Shultz, Francine Siegel, Marlene Siems, Ratanakorn Skelton, Carl Smith, Jannie Smith, Vickie Smith, William Snedeker, Patrick Snyder, Edward Solis, Mary Soliz, Roger Sowinski, Cynthia Spencer, Stephen Stagg, Troy Staten, Frank Stein, Janet Stein, Linda Steiner, Wallace Stevenson, Robert Stewart, Gwen Stone, Phaedra Sunday, Rory Sundstrom, Edward Suter, Carol Swan, Sony Syamala, Richard Tafaya, Clarence Taylor, Catherine Thompson, Lois Thompson, Margrett Thompson, Vernon Thompson, Michael Titmuss, Nancy Titmuss, David Tomlin, Frank Torres, Colleen Tranquill, Von Trimble, Chuong Van Trong, Martha Turner, Loraine Turrell, Mildred J. Tweedy, Graham Tye, Scott Vandermolin, Louise Verdel, John Viccia, Steven Vig, Janet Vopinek, Kathy Walent, Linda Walker, J. Holland Wallis, Shirley Washington, Janice Welsh, Mary Wentworth, Betty Werner, Sally West, Dee Louise Whitney, Sharon Wilkins, Mark Williamson, Steve Willis, Shirley Woods, Benyam Yohannes, Tony Yutyatat, Catalina Zafra, Metro Zamito, Christina Zepeda, Andrew Zielinski, Michal Zookin. (Wetherall, Peter) (Entered: 12/31/2018)
01/03/2019	8	ORDER Granting 7 Stipulation for Extension of Time re 3 Motion to Dismiss (First Request). Signed by Judge James C. Mahan on 1/3/2019. (Copies have been distributed pursuant to the NEF – MR) (Entered: 01/03/2019)
01/09/2019	9	MOTION to Remand to State Court by Plaintiffs Elsie Ayers, Jack Ayers, Angel Barahona, Catherine Barber, Levelyn Barber. Responses due by 1/23/2019. (Wetherall, Peter) (Entered: 01/09/2019)
01/09/2019	10	STATUS REPORT RE REMOVAL; filed by Defendants Baxter Healthcare Corporation, McKesson Medical-Surgical Inc., Sicor, Inc., Teva Parenteral Medicines, Inc.. (Hymanson, Philip) (Entered: 01/09/2019)
01/23/2019	11	RESPONSE to 9 Motion to Remand to State Court by Defendants Baxter Healthcare Corporation, McKesson Medical-Surgical Inc., Sicor, Inc., Teva Parenteral Medicines, Inc.. Replies due by 1/30/2019. (Hymanson, Philip) (Entered: 01/23/2019)
01/29/2019	12	REPLY to Response to 9 Motion to Remand to State Court by Plaintiffs Lidia Aldanay, Maridee Alexander, Carolyn Armstrong, Elsie Ayers, Jack Ayers, Angel Barahona, Catherine Barber, Levelyn Barber. (Wetherall, Peter) (Entered: 01/29/2019)
03/18/2019	13	**STRICKEN per 15 Order. (MR)** ~~ADDENDUM to 9 Motion to Remand to State Court by Plaintiffs Lidia Aldanay, Maridee Alexander, Carolyn Armstrong, Elsie Ayers, Jack Ayers, Angel Barahona, Catherine Barber, Levelyn Barber. (Wetherall, Peter)~~ (Entered: 03/18/2019)
03/26/2019	14	MOTION for Leave to File *Response to Plaintiffs' Supplemental Authority and Request for Judicial Notice of Supplemental Authority* re 13 Addendum by Defendants Baxter Healthcare Corporation, McKesson Medical-Surgical Inc., Sicor, Inc., Teva Parenteral Medicines, Inc.. (Hymanson, Philip) (Entered: 03/26/2019)
04/12/2019	15	ORDER. IT IS HEREBY ORDERED, ADJUDGED, and DECREED that 9 plaintiffs' motion to remand be, and the same hereby is, GRANTED. IT IS FURTHER ORDERED that 14 defendants' motion for leave to file surreply be, and the same hereby is, DENIED

		IT IS FURTHER ORDERED that 3 defendants' motion to dismiss be, and the same hereby is, DENIED without prejudice. The clerk shall strike 13 plaintiffs' surreply and close the case accordingly. Signed by Judge James C. Mahan on 4/12/2019. (Copies have been distributed pursuant to the NEF – cc: Certified Copy of Order and Docket Sheet sent to State Court – MR) (Entered: 04/12/2019)

I hereby attest and certify on 4/12/2019 that the foregoing document is a full, true and correct copy of the original on file in my legal custody.

CLERK, U.S. DISTRICT COURT
DISTRICT OF NEVADA

By MONICA REYES Deputy Clerk

CLERK, U.S. DISTRICT COURT
DISTRICT OF NEVADA
LOYD D. GEORGE U.S. COURTHOUSE
00 LAS VEGAS BLVD. SO. – RM 1334
LAS VEGAS, NV 89101

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EXHIBIT 3

EXHIBIT 3

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

* * *

ABADJIAN, SOSSY, et al., Plaintiff(s), v. TEVA PARENTERAL MEDICINES, INC., et al., Defendant(s).	Case No. 2:18-CV-2321 JCM (NJK) ORDER

Presently before the court is individual plaintiffs' motion to remand. (ECF No. 21). Defendants Baxter Healthcare Corporation; McKesson Medical-Surgical Inc.; Sicor, Inc.; and Teva Parenteral Medicines, Inc. (collectively "defendants") responded (ECF No. 23), to which plaintiffs replied (ECF No. 24).

Also before the court is defendants' motion for leave to file response to plaintiffs' supplemental authority (ECF No. 25) and request for judicial notice of supplemental authority (ECF No. 26). Plaintiffs have not replied.

I. Facts

The plaintiffs in this action are individuals who received medical care at the Endoscopy Center ("clinic") located at 700 Shadow Land, Clark County, Nevada. (ECF No. 1). Defendants supplied the clinic with medical products that the clinic would use in providing various anesthesia services. *Id.* The clinic improperly administered defendants' medical products by re-using injection syringes and anesthesia bottles, which created a foreseeable risk of infection or cross-contamination. *Id.*

James C. Mahan
U.S. District Judge

On or about February 28, 2008, the Southern Nevada Health District sent plaintiffs and approximately 60,000 others a letter informing them that the clinic placed them at a risk of possible exposure to bloodborne pathogens. *Id.* The Health District recommended that plaintiffs' get tested for hepatitis C, hepatitis B, and HIV. *Id.* Plaintiffs followed the Health District's recommendation and eventually discovered that they did not contract any of the aforementioned diseases. *Id.*

Plaintiffs believe that defendants' improper packaging of their medical products caused the clinic to improperly re-use syringes and bottles. *Id.* On April 11, 2016, plaintiffs offered to settle their claims in exchange for $4,252,500, which amounts to $2,500 per plaintiff. (ECF No. 9). Defendants rejected plaintiffs' offer. *Id.*

On October 1, 2018, plaintiffs initiated this action in state court, asserting four causes of action: (1) strict product liability; (2) breach of the implied warranty of fitness for a particular purpose; (3) negligence; and (4) violation of the Nevada Deceptive Trade Practices Act. (ECF No. 1).

On December 10, 2018, defendants removed this action to federal court. *Id.* The court now determines whether it has subject matter jurisdiction.

II. Legal Standard

Pursuant to 28 U.S.C. § 1441(a), "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending." 28 U.S.C. § 1441(a). "A federal court is presumed to lack jurisdiction in a particular case unless the contrary affirmatively appears." *Stock West, Inc. v. Confederated Tribes of Colville Reservation*, 873 F.2d 1221, 1225 (9th Cir. 1989).

Upon notice of removability, a defendant has thirty days to remove a case to federal court once he knows or should have known that the case was removable. *Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1250 (9th Cir. 2006) (citing 28 U.S.C. § 1446(b)(2)). Defendants are not charged with notice of removability "until they've received a paper that gives them enough information to remove." *Id.* at 1251.

Specifically, "the 'thirty day time period [for removal] . . . starts to run from defendant's receipt of the initial pleading only when that pleading affirmatively reveals on its face' the facts necessary for federal court jurisdiction." *Id.* at 1250 (quoting *Harris v. Bankers Life & Casualty Co.*, 425 F.3d 689, 690–91 (9th Cir. 2005) (alterations in original)). "Otherwise, the thirty-day clock doesn't begin ticking until a defendant receives 'a copy of an amended pleading, motion, order or other paper' from which it can determine that the case is removable. *Id.* (quoting 28 U.S.C. § 1446(b)(3)).

A plaintiff may challenge removal by timely filing a motion to remand. 28 U.S.C. § 1447(c). On a motion to remand, the removing defendant faces a strong presumption against removal, and bears the burden of establishing that removal is proper. *Sanchez v. Monumental Life Ins. Co.*, 102 F.3d 398, 403–04 (9th Cir. 1996); *Gaus v. Miles, Inc.*, 980 F.2d 564, 566–67 (9th Cir. 1992).

III. Discussion

As a preliminary matter, the court notes that plaintiffs have filed an addendum in support of their motion to remand (ECF No. 25) and defendants now move for leave to file their own response (ECF No. 26). Because the filings pertain to legal authority that is not binding on this court, the court will strike plaintiffs addendum (ECF No. 25) and deny defendants' motion (ECF No. 26).

Plaintiffs move to remand, arguing that the court does not have diversity jurisdiction. (ECF No. 21). Defendants' contend that the court has both diversity and federal question jurisdiction. (ECF Nos. 1, 23). The court will address both of defendants' purported grounds for subject matter jurisdiction in turn.

a. Diversity jurisdiction

First, the parties do not dispute that there is diversity of citizenship. (*See* ECF Nos. 1, 10, 21, 23, 24). Teva Parenteral Medicines, Inc., and SICOR, Inc. are incorporated in Delaware, and their principal places of business are in California. (ECF No. 1 at 9). Baxter Healthcare Corporation is incorporated in Delaware, and its principal place of business is in Illinois. *Id.* Plaintiffs are all residents of Nevada. *Id.* Thus, complete diversity exists between the parties.

The only issue before the court is whether the amount in controversy satisfies 28 U.S.C. § 1332, which allows federal courts to exercise diversity jurisdiction in civil actions between citizens of different states where the amount in controversy exceeds $75,000. *See* 28 U.S.C. § 1332(a). "In determining the amount in controversy, courts first look to the complaint. Generally, 'the sum claimed by the plaintiff controls if the claim is apparently made in good faith.'" *Ibarra v. Manheim Invests., Inc.* 775 F.3d 1193, 1197 (9th Cir. 2015) (citing *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 289 (1938)). At the time of removal, parties may submit supplemental evidence to show that the amount in controversy is in excess of $75,000. *Id.* (citing *Singer v. State Farm Mut. Auto. Ins. Co.*, 116 F.3d 373, 377 (9th Cir. 1997).

Plaintiffs allege in the complaint that their claims are each valued in excess of $15,000 in general damages. (ECF No. 1). This figure is well below the amount in controversy threshold under § 1332(a) and defendants have not submitted any evidence showing that a greater amount is in dispute.

Nevertheless, defendants contend that the amount in controversy is in excess of $75,000 because plaintiffs also seek attorney's fees and punitive damages. (ECF No. 11). The court now must determine whether defendants have proven by a preponderance of the evidence that punitive damages and attorney's fees, coupled with general damages, will exceed the jurisdiction minimum. *See Sanchez v. Monumental Life Ins. Co.*, 102 F.3d 398, 403-04 (9th Cir. 1996).

i. Punitive damages

Courts consider punitive damages in determining the amount in controversy when a plaintiff can recover punitive damages as a matter of law. *Gibson v. Chrysler Corp.*, 261 F.3d 927, 945 (9th Cir. 2001). Under Nevada law, a plaintiff can recover punitive damages only by proving with clear and convincing evidence that the defendant is guilty of oppression, fraud, or malice. Nev. Rev. Stat. 42.005(1). In light of NRS 42.005, the court will consider punitive damages for jurisdictional purposes.

Courts generally look to jury awards in analogous cases in determining how to consider punitive damages towards satisfying the jurisdictional minimum. *See Campbell v. Hartford Life Ins. Co.*, 825 F. Supp. 2d 1005, 1008 (E.D. Cal. 2011). Here, defendants have not provided any

factual support, other than citing statutes, pertaining to the probable amount of punitive damages. Therefore, defendants have not shown by a "preponderance of the evidence" that punitive damages increase the amount in controversy. *See Sanchez*, 102 F.3d at 404.

ii. Attorney's fees

Courts consider attorney's fees in determining the amount in controversy if a plaintiff can recover such fees pursuant to a contract or statute. *Galt G/S v. JSS Scandinavia*, 142 F.3d 1150, 1156 (9th Cir. 1998). The Nevada Supreme Court has held that "in the absence of legislation specifically providing for attorney's fees, such fees cannot be awarded." *Consumers League v. Southwest Gas*, 576 P.2d 737 (Nev. 1978). Notably, Nevada law does not expressly provide for attorney's fees in class action suits. "It is for the legislature . . . to make a special provision for class actions within NRS 18.010." *Schouweiler v. Yancey Co.*, 712 P.2d 786, 788 (Nev. 1985) (holding that the district court was correct in denying the award of attorney's fees pursuant to NRS 18.010).

Nevada law does allow courts to award attorney's fees when (1) the prevailing party has not recovered more than $20,000 or (2) when the opposing party's defense was "brought or maintained without reasonable grounds or to harass the prevailing party." Nev. Rev. Stat. 18.010(2). Because each plaintiff appears to seek less than $20,000 in damages, the court will consider attorney's fees in determining the amount in controversy.

Defendants' argue that attorney's fees will spike the cost of this action because this case involves hundreds of plaintiffs. (ECF No. 11). The complex nature of this lawsuit compels the court to conclude that plaintiffs will incur significant attorney's fees. However, defendants once again have not provided evidence showing the extent that attorney's fees increase the amount in controversy. Indeed, the court does not find that attorney's fees would quadruple or quintuple the ultimate award.

In sum, defendants have not shown by a preponderance of the evidence an amount in controversy in excess of $75,000. Accordingly, the court cannot exercise subject matter jurisdiction under § 1332(a).

. . .

b. Federal question jurisdiction

The "well-pleaded complaint rule" governs federal question jurisdiction. This rule provides that district courts can exercise jurisdiction under 28 U.S.C. § 1331 only when a federal question appears on the face of a well-pleaded complaint. *See, e.g.*, *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). Thus, a plaintiff "may avoid federal jurisdiction by exclusive reliance on state law." *Id.* Moreover, "an anticipated or actual federal defense generally does not qualify a case for removal[.]" *Jefferson County v. Acker*, 527 U.S. 423, 431 (1999).

The well-pleaded complaint rule does not require a plaintiff to assert a federal cause of action. District court also have jurisdiction over state law claims that raise "some substantial, disputed question of federal law[.]" *Indep. Living Ctr. of Southern California, Inc. v. Kent*, 909 F.3d 272, 279 (9th Cir. 2018). Indeed, federal question jurisdiction exists when a federal issue is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disturbing the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

Defendants argue that plaintiffs' state tort claims, which allege that defendants improperly packaged medical products, raise a substantial issue of federal law because the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, governs the packaging of medical products. (ECF No. 11). The court disagrees.

In *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, the Supreme Court held that state law claims which allege violations of the FDCA do not raise a substantial federal question because Congress did not intend to create a private right of action for violation of the FDCA. *Wander v. Kaus*, 304 F.3d 856, 859 (9th Cir. 2002) (citing *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 808 (1986)). As the circumstances of this case fall well within *Merrell Dow*, the court concludes that plaintiffs' complaint does not raise a substantial federal question.

The court notes that defendants' arguments are unclear, incoherent, and at times confused. Some paragraphs from defendants' brief appear to assert that the court has jurisdiction because the FDCA preempts plaintiffs' state law claims. To ensure complete adjudication of all pertinent issues that the parties raise, the court will consider this argument.

The "complete preemption doctrine" allows district courts to exercise federal question jurisdiction over state law claims when a federal statute completely preempts the relevant state law. *Balcorta v. Twentieth Century-Fox Film Corp.*, 208 F.3d 1102, 1107 (9th Cir. 2000) (citation omitted). Courts consider the factual allegations in the complaint and the petition of removal to determine whether federal law completely preempts a state law claim. *Schroeder v. Trans World Airlines, Inc.*, 702 F.2d 189, 191 (9th Cir. 1983).

It is well established that the FDCA does not completely preempt state law. *See Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1259–60 (D. Or. 2011); *see also Perez v. Nidek Co. Ltd.*, 657 F. Supp. 2d 1156, 1161 (S.D. Cal. 2009); *see also Alaska v. Eli Lilly & Co.*, No. 3:06-cv-88 TMB, 2006 WL 2168831 at *3–4 (D. Ala July 28, 2006). Therefore, the court does not have federal question jurisdiction under the complete preemption doctrine.

IV. Conclusion

The court does not have subject matter jurisdiction because the amount in controversy is not in excess of $75,000, plaintiffs' complaint does not raise a substantial federal question, and the FDCA does not completely preempt plaintiffs' state law claims.

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that plaintiffs' motion to remand (ECF No. 21) be, and the same hereby is, GRANTED.

IT IS FURTHER ORDERED that defendants' motion for leave to file a response (ECF No. 26) be, and the same hereby is, DENIED, consistent with the foregoing.

IT IS FURTHER ORDERED that defendants' motion to dismiss (ECF No. 8) be, and the same hereby is, DENIED without prejudice.

IT IS FURTHER ORDERED that the matter of *Abadjian et al. v. Teva Parental Medicines, Inc. et al.*, case number 2:18-cv-02321-JCM-VCF, be, and the same hereby is, REMANDED.

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James C. Mahan
U.S. District Judge

The clerk shall strike plaintiffs' addendum (ECF No. 25) and close the case accordingly.

DATED August 23, 2019.

UNITED STATES DISTRICT JUDGE

James C. Mahan
U.S. District Judge

EXHIBIT 4

EXHIBIT 4

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

YVETTE ADAMS, *et al.*, Plaintiffs, vs. TEVA PARENTERAL MEDICINES, INC., *et al.*, Defendants.	Case No.: 2:18-cv-02305-GMN-BNW **ORDER**

Pending before the Court is the Motion to Remand, (ECF No. 9),[1] filed by Plaintiffs Yvette Adams, Margaret Adymy, Thelma Anderson, John Andrews, Maria Artiga, Lupita Avila-Medel, Henry Ayoub, Joyce Bakkedahl, Donald Becker, James Bedino, Edward Benavente, Margarita Benavente, Susan Biegler, Kenneth Burt, Margaret Calavan, Marcelina Castaneda, Vickie Cole-Campbell, Sherrill Coleman, Nancy Cook, and James Duarte (collectively "Plaintiffs"). Defendants Teva Parenteral Medicines, Inc., Sicor, Inc., Baxter Healthcare Corporation, and McKesson Medical Surgical, Inc. (collectively "Defendants") filed a Response, (ECF No. 14), and Plaintiffs filed a Reply, (ECF No. 15).

For the reasons that follow, the Court **GRANTS** Plaintiffs' Motion to Remand.

I. BACKGROUND

Plaintiffs are adult individuals who underwent treatment at a medical center in Las Vegas, Nevada (the "Clinic") between 2004 and 2008 for endoscopy procedures. (*See* Compl. ¶¶ 7–8, Ex. A to Pet. for Removal, ECF No. 1-1). Under the care of the Clinic's health care

[1] Prior to Plaintiffs filing the instant Motion, Defendants filed a Motion to Dismiss, (ECF No. 4). Subsequently, the Court granted the parties' stipulation to stay the briefing schedule on the Motion to Dismiss until the instant Motion to Remand is resolved, (ECF Nos. 8, 13). Because the Court remands this action in this Order, the Motion to Dismiss is **DENIED as moot**.

providers, Plaintiffs were injected with propofol, an anesthetic drug manufactured, marketed, distributed, and sold by Defendants to the Clinic. (*Id.* ¶¶ 2–4, 7, 12).

On February 28, 2008, the Southern Nevada Health District sent a letter to 60,000 former Clinic patients, including Plaintiffs, stating they were at risk of exposure to bloodborne pathogens. (*Id.* ¶ 15). The letter recommended that all persons who received an injection at the [Clinic] between March of 2004 and January of 2008," as well as their spouses, be tested for Hepatitis B, Hepatitis C, and HIV. (*Id.* ¶ 11). Plaintiffs obtained the recommended testing and ultimately learned they were infection-free. (*Id.* ¶ 13). In doing so, Plaintiffs incurred medical bills and other out-of-pocket expenses, and endured emotional distress, anxiety, and fear during the pendency of their respective test results. (*Id.* ¶ 17). According to the Complaint, at all relevant times to this action, Defendants knew or should have known that the Clinic's practices "involved the re-use of injection syringes and anesthesia bottles," creating a "foreseeable risk of infection/cross-contamination between patients with whom said syringes and anesthesia bottles were shared." (*Id.* ¶ 9).

Plaintiffs filed this action in state court on July 26, 2018, bringing the following causes of action against Defendants: (1) strict product liability; (2) breach of the implied warranty of fitness for a particular purpose; (3) negligence; (4) violation of the Nevada Deceptive Trade Practices Act; and (5) punitive damages. (*Id.* ¶¶ 19–60). On December 10, 2018, Defendants removed the case here on the grounds of diversity and federal-question jurisdiction. (*See* Pet. for Removal, ECF No. 1). Shortly thereafter, Plaintiffs filed the instant Motion requesting that the Court remand this action back to state court. (*See* Mot. to Remand, ECF No. 9).

II. LEGAL STANDARD

Federal courts are courts of limited jurisdiction, possessing only those powers granted by the Constitution and by statute. *See United States v. Marks*, 530 F.3d 799, 810 (9th Cir. 2008) (citation omitted). For this reason, "[i]f at any time before final judgment it appears that the

district court lacks subject-matter jurisdiction, the case shall be remanded." 28 U.S.C. § 1447(c). District courts have subject-matter jurisdiction in two instances. First, district courts have subject-matter jurisdiction over civil actions that arise under federal law. 28 U.S.C. § 1331. Second, district courts have subject-matter jurisdiction over civil actions where no plaintiff is a citizen of the same state as a defendant and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332(a).

A defendant may remove an action to federal court only if the district court has original jurisdiction over the matter. 28 U.S.C. § 1441(a). "Removal statutes are to be 'strictly construed' against removal jurisdiction." *Nevada v. Bank of Am. Corp.*, 672 F.3d 661, 667 (9th Cir. 2012) (quoting *Syngenta Crop Prot., Inc. v. Henson*, 537 U.S. 28, 32 (2002)). "The 'strong presumption against removal jurisdiction means that the defendant always has the burden of establishing that removal is proper,' and that the court resolves all ambiguity in favor of remand to state court." *Hunter v. Philip Morris USA*, 582 F.3d 1039, 1042 (9th Cir. 2009) (quoting *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir.1992) (per curiam)).

III. DISCUSSION

Plaintiffs move to remand this action on the basis that the Court is without subject-matter jurisdiction. (*See generally* Mot. to Remand, ECF No. 9). Defendants oppose Plaintiffs' Motion, contending this Court enjoys both diversity jurisdiction, as well as federal-question jurisdiction. (Defs.' Resp. to Mot. to Remand ("Resp.") 4:6–9:13, ECF No. 14).

The Court begins with diversity jurisdiction, followed by federal-question jurisdiction.

A. Diversity Jurisdiction

Federal courts have diversity jurisdiction over all civil actions in which the amount in controversy: (1) exceeds the sum or value of $75,000; and (2) is between citizens of different states. 28 U.S.C. § 1332(a). In the present case, it is undisputed that complete diversity of citizenship exists because no Plaintiff is a citizen of the same state as any Defendant. (*See* Pet.

for Removal ¶¶ 8–11, ECF No. 1); (Compl. ¶¶ 1–4, ECF No. 1-1). Therefore, the question is whether the amount in controversy exceeds $75,000.

1. Amount in Controversy

In determining the amount in controversy, the Court's "starting point is whether it is facially apparent from the complaint that the jurisdictional amount is in controversy." *Lowdermilk v. United States Bank Nat'l Ass'n*, 479 F.3d 994, 998 (9th Cir. 2007). "[W]hen a complaint filed in state court alleges on its face an amount in controversy sufficient to meet the federal jurisdictional threshold, such requirement is presumptively satisfied unless it appears to a 'legal certainty' that the plaintiff cannot actually recover that amount." *Guglielmino v. McKee Foods Corp.*, 506 F.3d 696, 699 (9th Cir. 2007) (quoting *Sanchez v. Monumental Life Ins. Co.*, 102 F.3d 398, 402 (9th Cir. 1996)). "Where it is not facially evident from the complaint that more than $75,000 is in controversy, the removing party must prove, by a preponderance of the evidence, that the amount in controversy meets the jurisdictional threshold." *Matheson v. Progressive Specialty Ins. Co.*, 319 F.3d 1089, 1090–91 (9th Cir. 2003) (per curiam).

Here, the amount in controversy is not facially evident from the Complaint. Plaintiffs' prayer for relief includes a request for general damages "in excess of $15,000," and unspecified sums for punitive damages, attorneys' fees, and costs. (*See* Compl. 13:7–13). Though Plaintiffs request special damages "in excess of $15,000," within four of the Complaint's substantive claims, those requests employ identical language and expressly seek the same damages arising from the same injury. (*See id.* ¶ 41) ("Plaintiffs have incurred special damages in the form of medical expense as well as emotional distress, anxiety, and fear during the pendency of their test results and for some time after . . . ."); (*see also id.* ¶¶ 48, 53, 56) (same). Given the overlapping requested relief, the value of special damages on the face of the Complaint is uncertain. *See Singh v. Glenmark Phargenerics, Inc.*, No. 2:14-cv-154-GMN-CWH, 2014 WL 4231364, at *2 (D. Nev. Aug. 26, 2014) ("[T]hese causes of action seek recovery for the same

injuries. Therefore, it would be fallacious to mechanically add these values in determining the total amount in controversy, as Plaintiffs cannot recover multiple times for the same harm.") (citing *Elyousef v. O'Reilly & Ferrario, LLC*, 443, 245 P.3d 547, 549 (Nev. 2010) ("[A] plaintiff may not recover damages twice for the same injury simply because he or she has two legal theories.")).

Aside for the $15,000 Plaintiffs seek in general damages and the $15,000 requested in special damages, the remaining categories of relief do not assign dollar amounts. Thus, because the jurisdictional amount is not facially evident, Defendants must show, by a preponderance of the evidence, that it is more likely than not that $75,000 is at stake. *Matheson*, 319 F.3d at 1090–91. On this point, Defendants point to Plaintiffs' prayer for punitive damages and attorneys' fees to satisfy the jurisdictional threshold.

a. Punitive Damages

Where punitive damages are recoverable under state law, such damages may be considered in determining the amount in controversy. *Gibson v. Chrysler Corp.*, 261 F.3d 927, 945 (9th Cir. 2001). Because Nevada permits recovery of punitive damages, NRS 42.005, Plaintiffs' prayer for the same may be considered in calculating the amount in controversy. In situations where the value of punitive damages is unclear, "[t]he defendant bears the burden of actually proving the facts to support jurisdiction." *Gaus*, 980 F.2d at 567. To establish the probable amount of punitive damages, a defendant must come forward with evidence, which may include jury verdicts or settlements in substantially similar cases. *See, e.g.*, *Flores v. Standard Ins. Co.*, No. 3:09-cv-00501-LRH-RAM, 2010 WL 185949, at *5 (D. Nev. Jan. 15, 2010); *Campbell v. Hartford Life Ins. Co.*, 825 F. Supp. 2d 1005, 1008 (E.D. Cal. 2011).

Here, Defendants' argument with respect to punitive damages is too speculative to be credited. Defendants contend that the Complaint's reference to NRS 42.005, which permits an award of up to $300,000 when a plaintiff's compensatory damages do not exceed $100,000,

establishes that more than $75,000 is in on controversy. (Resp. 6:9–17). Defendants, however, neglect to support its argument with facts from this case or any analogous case to demonstrate the likelihood of a punitive damages award. "Mere allusion, in the absence of supplementary evidence, is insufficient for the Court to determine a probable punitive damages amount." *Cayer v. Vons Cos.*, No. 2:16-cv-02387-GMN-NJK, 2017 WL 3115294, at *3 (D. Nev. July 21, 2017); *see also Hannon v. State Farm Mut. Auto. Ins. Co.*, No. 2:14-cv-1623-GMN-NJK, 2014 WL 7146659, at *3 (D. Nev. Dec. 12, 2014) (excluding punitive damages in the amount in controversy given the defendant's "fail[ure] to identify any particular facts or allegations which might warrant a large punitive damage award."). Because Defendants have not met their burden, the Court will not include punitive damages in determining the amount in controversy.

b. Attorneys' Fees

"[W]here an underlying statute authorizes an award of attorneys' fees, either with mandatory or discretionary language, such fees may be included in the amount in controversy." *Guglielmino*, 506 F.3d at 700 (quoting *Galt G/S v. JSS Scandinavia*, 142 F.3d 1150, 1156 (9th Cir. 1998)). "This Court considers attorneys' fees to be within the amount in controversy if the removing party: (1) identifies 'an applicable statute which could authorize an award of attorneys' fees and (2) provide[s] an estimate as to the time the case will require and opposing counsel's hourly billing rate.'" *Cayer*, 2017 WL 3115294, at *2 (quoting *Hannon*, 2014 WL 7146659, at *2).

Here, Defendants neither identify a statute nor provide an estimate of Plaintiffs' counsel's billing rate. Instead, Defendants limit their argument to hypothesizing that because the parties have been in settlement negotiations going back to April 2016, Plaintiffs' attorneys' fees "as a practical matter" have likely surged. (Resp. 6:5–8). Such speculation is not enough to warrant inclusion of attorneys' fees in the amount in controversy. *See, e.g.*, *Surber v. Reliance Nat. Indent. Co.*, 110 F. Supp. 2d 1227, 1232 (N.D. Cal. 2000) (declining to add

attorneys' fees to the amount-in-controversy calculation where "Defendant has not estimated the amount of time that the case will require, nor has it revealed plaintiff's counsel's hourly billing rate."); *see also Wilson v. Union Sec. Life Ins. Co.*, 250 F. Supp. 2d 1260, 1264 (D. Idaho 2003) (stating a defendant "must do more than merely point to [a plaintiff's] request for attorney's fees; upon removal it must demonstrate the probable amount of attorney's fees").

To summarize, Defendants have not met their burden of showing, by a preponderance of the evidence, that more than $75,000 is at stake in this case. Accordingly, the Court cannot exercise diversity jurisdiction over this matter.

B. Federal-Question Jurisdiction

28 U.S.C. § 1331 vests federal district courts with original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." "To remove a case as one falling within federal-question jurisdiction, the federal question ordinarily must appear on the face of a properly pleaded complaint; an anticipated or actual federal defense generally does not qualify a case for removal." *Jefferson Cty. v. Acker*, 527 U.S. 423, 430–31 (1999); *see also Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987) ("The rule makes the plaintiff the master of the claim; he or she may avoid federal jurisdiction by exclusive reliance on state law.").

Defendants do not contest that the Complaint, on its face, is solely comprised of state-law claims. Rather, Defendants appear to advance two distinct theories to support federal-question jurisdiction: (1) Plaintiffs' claims are preempted because they rely on state-law duties that conflict with those imposed by federal law; and (2) the Complaint necessarily raises a substantial federal question because resolution of the claims requires examination of federal issues that fall within the exclusive authority of the U.S. Food and Drug Administration ("FDA"). (Resp. 6:19–9:13). The Court addresses each argument in turn.

1. Federal Preemption

According to Defendants, the Complaint necessarily raises a federal issue because the Supremacy Clause preempts Plaintiffs' state law claims. (*Id.* 7:18–23). Defendants explain that the wrongful conduct alleged—Defendants' improper packaging and distribution of propofol—is governed exclusively by the FDA, which has promulgated regulations establishing baseline manufacturing requirements for the preparation of drug products. (*Id.* 4:26–5:18) (citing 21 C.F.R. § 211). And because Plaintiffs' claims rely upon state-law duties that go beyond what the FDA requires, the issue of federal preemption is necessarily raised. (*Id.* 7:15–23, 8:11–9:13).

To the extent Defendants invoke "defensive preemption," the Court is unconvinced. It is well settled that "a case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption." *In re NOS Commc'ns*, 1357, 495 F.3d 1052, 1057 (9th Cir. 2007) (emphasis in original) (quoting *Caterpillar*, 482 U.S. at 392). This rule applies "even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." *Caterpillar*, 482 U.S. at 392.

Insofar as Defendants advance a "complete preemption" argument, it necessarily fails. The U.S. Supreme Court has recognized that the "preemptive force of some statutes is so strong that they 'completely preempt' an area of state law." *Balcorta v. Twentieth Century-Fox Film Corp.*, 208 F.3d 1102, 1107 (9th Cir. 2000) (citing *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987)). "Once an area of state law has been completely pre-empted, any claim purportedly based on that pre-empted state law is considered, from its inception, a federal claim, and therefore arises under federal law." *Caterpillar*, 482 U.S. at 393 (internal citation and quotation marks omitted). Complete preemption is "rare" and has only been endorsed by the U.S. Supreme Court with respect to three federal statutes: § 301 of the Labor Relations Act; §§ 85 and 86 of the National Bank Act; and § 502 of the Employee Retirement Income Security Act.

See Retail Prop. Tr. v. United Bhd. of Carpenters & Joiners of Am., 768 F.3d 938, 948 n.5 (9th Cir. 2014).

In the present case, Defendants have not made any showing as to why the Federal Food, Drug, and Cosmetic Act ("FDCA") should be counted as a completely preemptive statutory scheme. In any event, the Court is persuaded by the overwhelming weight of authority holding that Congress's endorsement of *some* state-law claims arising from FDCA regulations conclusively defeats arguments in favor of complete preemption. *See, e.g.*, *Bridges v. Teva Parenteral Medicines, Inc.*, No. 2:18-cv-02310-JCM-VCF, 2019 WL 1585109, at *4 (D. Nev. Apr. 12, 2019) (collecting Ninth Circuit district court cases holding that "the FDCA does not completely preempt state law"); *see also Mihok v. Medtronic, Inc.*, 119 F. Supp. 3d 22, 32 (D. Conn. 2015) ("Congress anticipated and approved of limited state court analysis and application of the FDA regulations when it decided not to completely preempt parallel state law claims.") (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding that 21 U.S.C. § 360 of the FDCA does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel' rather than add to, federal requirements.")).

Next, the Court turns to Defendants' contention that Plaintiffs' claims necessarily turn on a question of federal law.

2. Jurisdiction Under *Gunn-Grable*

The U.S. Supreme Court has identified a "special and small category" of cases that arise under federal-question jurisdiction notwithstanding a complaint's sole reliance on state-law claims. *Gunn v. Minton*, 568 U.S. 251, 258 (2013) (citation omitted). "Federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Id.* (citing *Grable & Sons Metal Prod., Inc. v. Darue Eng'g &*

Mfg., 545 U.S. 308, 313–14 (2005)). To support federal-question jurisdiction, all four *Gunn-Grable* requirements must be satisfied. *Id.*

Defendants contend that the Complaint requires examination of the FDCA's "duty of sameness," under 21 U.S.C. § 355 and 21 C.F.R. § 314, which requires that generic drug manufactures label their products identically to the respective brand manufacturer's label. (Resp. 5:23–6:1). According to Defendants, this duty "applies to every portion of Plaintiffs' complained-of conduct, including labeling, warnings, route of administration, dosage form, and strength." (*Id.* 6:1–3). Therefore, because the duty of sameness required that Defendants' labeling conform to that of the brand-name product, the Complaint necessarily touches upon Defendants' compliance with federal law. (*Id.* 6:3–17).

The problem for Defendants is that the Complaint does not allege that Defendants violated the FDCA's duty of sameness, or any federal duty for that matter.[2] Tellingly, Defendants do not cite to any portion of the Complaint for this proposition. Even if Plaintiffs raised the FDCA or the duty of sameness as an element of a claim, that would still not end the federal-question inquiry. For one thing, it is axiomatic that "the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction." *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 813 (1986). Furthermore, it is well established that "[w]hen a claim can be supported by alternative and independent theories—one of which is a state law theory and one of which is a federal law theory—federal question jurisdiction does not attach because federal law is not a necessary element of the claim." *Bank of Am. Corp.*, 672 F.3d at 675 (quoting *Rains v. Criterion Sys., Inc.*, 80 F.3d 339, 346 (9th Cir.

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[2] On this basis, Defendants' proffered supplemental authority is readily distinguishable. *See Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179, 183–84 (E.D.N.Y. 2012) (holding a federal issue was necessarily raised in the FDCA context where the complaint repeatedly and expressly alleged the "ongoing federal duty of sameness," as elements of the state-law claims). Additionally, *Bowdrie* concerned a generic manufacturer's failure to update its labeling to be consistent with the brand-name manufacturer's modified label. *Id.* at 181. In this case, by contrast, no such facts are alleged.

1996)). Indeed, each of Plaintiffs' claims refer only to common law duties under Nevada law and, consequently, do not appear to require federal analysis for their resolution. As Defendants have not articulated how any *specific* claim necessitates resort to federal law, Defendants have failed to meet their burden of showing otherwise. *See Cruz v. Preferred Homecare*, No. 2:14-cv-00173-MMD-CWH, 2014 WL 4699531, at *3 (D. Nev. Sept. 22, 2014) (rejecting the defendants' reliance on FDA regulation to establish the first *Gunn-Grable* element as "wholly insufficient, especially when contrasted with *Grable* and *Gunn*, in which the removing parties demonstrated that plaintiffs' *specific* claims hinged on a court's adjudication of a federal issue.") (emphasis in original).

Thus, Defendants have failed to establish the first element of the *Gunn-Grable* test. As the party asserting federal jurisdiction, Defendants bear the burden of showing removal is proper. *Gaus*, 980 F.2d 566. This burden is of enhanced significance in this context, where the weight of authority suggests no federal-question jurisdiction exists. *See, e.g.*, *Merrell Dow*, 478 U.S. at 817 (holding that a complaint's state-law claims against a drug manufacturer, premised upon FDCA misbranding violations, do not support federal-question jurisdiction); *Grable*, 545 U.S. at 316–20 (discussing *Merrell Dow*'s holding and reiterating "if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action."); *Burrell v. Bayer Corp.*, 918 F.3d 372, 381 (4th Cir. 2019) (concluding a plaintiff's state-law claims regarding FDA-regulated medical devices do not satisfy the third and fourth prongs of *Gunn-Grable*, and expressing doubt as to whether such claims necessarily raise federal issues under the first prong); *see also Nunes v. Affinitylifestyles.com, Inc.*, No. 2:16-cv-02265-APG-NJK, 2017 WL 359178 (D. Nev. Jan. 23, 2017); *Brandle v. McKesson Corp.*, No. C 12-cv-05970 WHA, 2013 WL 1294630 (N.D. Cal. Mar. 28, 2013). Because Defendants have not put forth a thorough, meaningful case

for application of the *Gunn-Grable* exception, the strong presumption against removal jurisdiction remains undisturbed.

In short, Defendants have not satisfied the Court that it may exercise diversity jurisdiction or federal-question jurisdiction. Consequently, this action must be remanded back to state court for want of subject-matter jurisdiction. Plaintiffs' Motion to Remand is therefore granted.

IV. CONCLUSION

IT IS HEREBY ORDERED that Plaintiffs' Motion to Remand, (ECF No. 9), is **GRANTED**.

IT IS FURTHER ORDERED that Defendants' Motion to Dismiss, (ECF No. 4), is **DENIED as moot**.

IT IS FURTHER ORDERED that this matter is hereby **REMANDED** to the Eighth Judicial District Court for the State of Nevada, County of Clark.

The Clerk of Court is instructed to close this case.

DATED this 26 day of August, 2019.

Gloria M. Navarro, Chief Judge
United States District Judge

EXHIBIT 5

ORIGINAL

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CLERK OF THE COURT

JGJV
ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT W. COTTLE, ESQ.
Nevada Bar No. 4576
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
MAINOR EGLET COTTLE
400 South Fourth Street, Suite 600
Las Vegas, NV 89101
(702) 450-5400
reglet@mainorlawyers.com
rcottle@mainorlawyers.com
badams@mainorlawyers.com

WILLIAM A. KEMP, ESQ.
Nevada Bar No. 1205
KEMP JONES COLTHARD
3800 Howard Hughes Parkway, 17th Floor
Las Vegas, NV 89169
(702) 385-6000

MAINOR EGLET COTTLE
TRIAL LAWYERS

DISTRICT COURT
CLARK COUNTY, NEVADA

HENRY CHANIN and LORRAINE CHANIN, husband and wife

Plaintiffs,

vs.

TEVA PARENTERAL MEDICINES, INC.,, formerly known as SICOR PHARMACEUTICALS, INC., a Delaware Corporation; SICOR, INC., a Delaware Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware Corporation

Defendants.

CASE NO.: A571172
DEPT.NO.: X

JUDGMENT UPON THE JURY VERDICT

JUDGMENT UPON THE JURY VERDICT

This action came on for trial before the Court and the jury, the Honorable Jessie Walsh, District Judge, presiding, and the issues having been duly tried and the jury having

duly rendered their verdict[1] and also special verdict[2],

IT IS ORDERED AND ADJUDGED that Plaintiffs, HENRY CHANIN and LORRAINE CHANIN, have and recover of the Defendants, TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., a Delaware Corporation, SICOR, INC., a Delaware Corporation; and BAXTER HEALTHCARE CORPORATION, a Delaware Corporation, the following sums:

COMPENSATORY DAMAGES:

Henry Chanin against TEVA & BAXTER	$ 3,250,000.00
Lorraine Chanin against TEVA & BAXTER	$ 1,850,000.00
Total Compensatory Damages:	**$ 5,100,000.00**

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' compensatory damages in the amount of Five Million One Hundred Thousand and 00/100 Dollars ($5,100,000.00), shall bear prejudgment interest in accordance with *Lee v. Ball, 116 P.3d 64*, (2005) at the rate of 5.25% per annum from the date of service of the Summons and Complaint, on October 6, 2008 through May 21, 2010 as follows:

PREJUDGMENT INTEREST:

10/06/08 through 05/28/10 = (599 days x $733.56 per day)	$ 439,402.44

PUNITIVE DAMAGES:

Henry and Lorraine Chanin against TEVA	$ 356,000,000.00
Henry and Lorraine Chanin against BAXTER	$ 144,000,000.00
Total Punitive Damages:	**$ 500,000,000.00**

1 Exhibit 1, Verdict
2 Exhibit 2, Special Verdict

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' punitive damages in the amount of Five Hundred Million and 00/100 Dollars ($500,000,000.00), shall bear postjudgment interest in accordance with *Lee v. Ball, 116 P.3d 64*, (2005) at the rate of 5.25% per annum from the time of entry of judgment until satisfied as follows:

POSTJUDGMENT INTEREST:

$71,917.80 per day

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs shall be awarded their costs of the action, the amount of which to be determined by the Court.

NOW, THEREFORE, Judgment Upon the Verdict in favor of Plaintiffs, HENRY AND LORRAINE CHANIN, is hereby given for Five Hundred Five Million, Five Hundred Thirty-Nine Thousand Four Hundred Two and 44/100 Dollars (**$505,539,402.44**) against Defendants which shall bear postjudgment interest at the current rate of 5.25% or $72,651.36 per day, until satisfied.

DATED this 1st day of June, 2010.

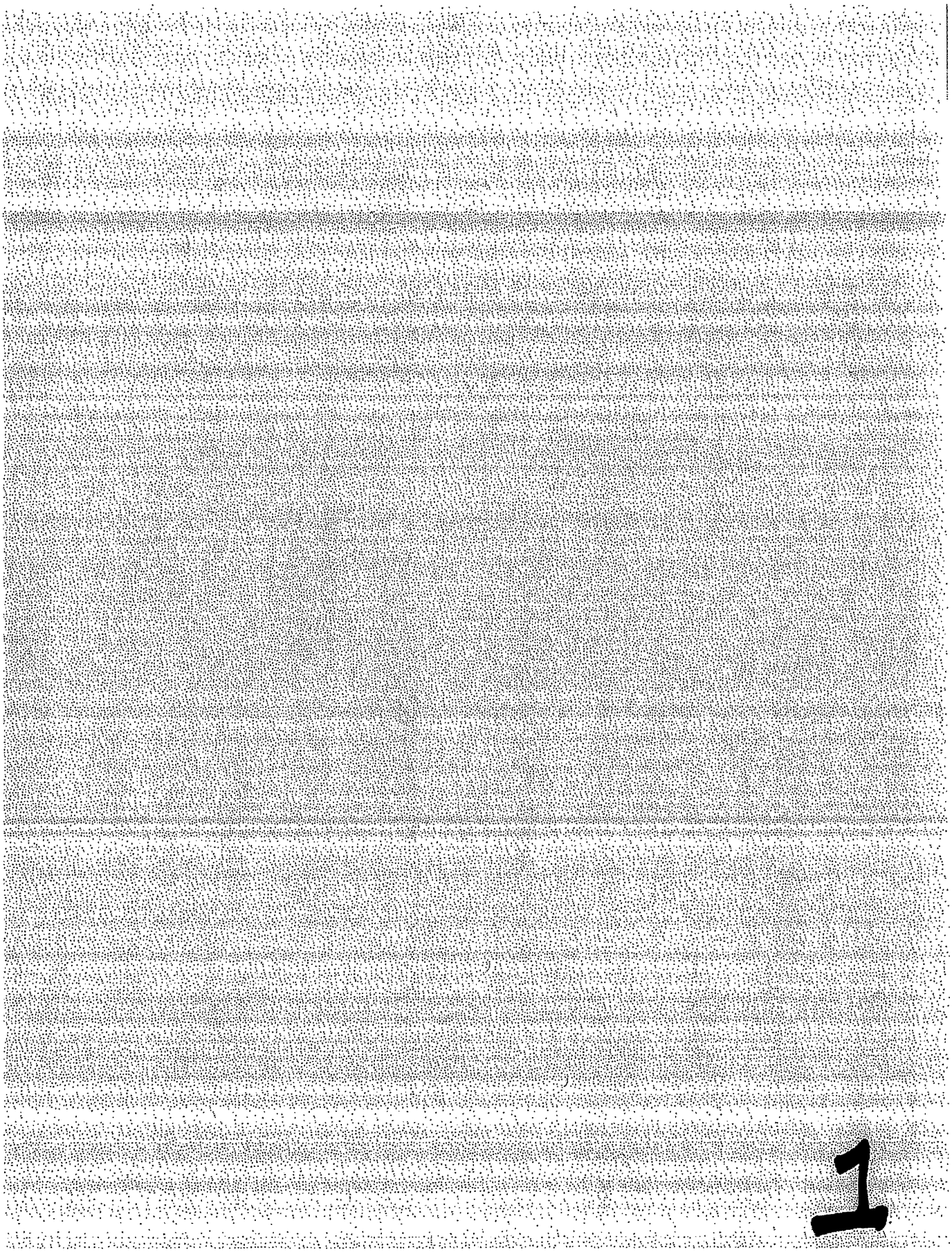
Jessie Walsh
DISTRICT COURT JUDGE

Respectfully Submitted by:

MAINOR EGLET COTTLE

ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT W. COTTLE, ESQ.
Nevada Bar No. 4576
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
400 South Fourth Street, Suite 600
Las Vegas, NV 89101

MAINOR EGLET COTTLE
TRIAL LAWYERS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STEVEN D. GRIERSON
CLERK OF THE COURT

MAY 05 2010

BY TERI BRAEGELMANN, DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

HENRY CHANIN and LORRAINE CHANIN, husband and wife Plaintiffs. vs. TEVA PARENTERAL MEDICINES, INC.,, formerly known as SICOR PHARMACEUTICALS, INC., a Delaware Corporation; SICOR, INC., a Delaware Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware Corporation Defendants.	CASE NO.: A571172 DEPT.NO.: X A571172 Henry Chanin, et al. v. Teva Parenteral Medicines, Inc., et al.

VERDICT FORM

If you find that the Defendant(s) are liable to the Plaintiff(s) set forth below under any one of the different liability claims for compensatory damages against such Defendants, check YES in the appropriate box and fill in the amount of compensation that you deem appropriate for each Plaintiff(s) for compensatory damages.

If you find that the Defendant(s) are not liable to the Plaintiff(s) set forth below under any of the different liability claims for compensatory damages, check NO in the appropriate box.

1. TEVA is liable to Henry Chanin for the following claims, if any:

   a. Strict liability for defective design.

   YES ___ NO X

   b. Failure to warn.

   YES X NO ___

   c. Breach of the implied warranty of fitness for a particular purpose.

   YES X NO ___

2. BAXTER is liable to Henry Chanin the following claims, if any:

a. Strict liability for defective design.

YES ___ NO X

b. Failure to warn.

YES X NO ___

c. Breach of the implied warranty of fitness for a particular purpose.

YES X NO ___

3. If you find TEVA is liable to HENRY CHANIN, you must also determine if TEVA is liable to LORRAINE CHANIN for loss of consortium.

YES X NO ___

4. If you find BAXTER is liable to HENRY CHANIN, you must also determine if BAXTER is liable to LORRAINE CHANIN for loss of consortium.

YES X NO ___

5. If you found TEVA is liable to HENRY CHANIN or to LORRAINE CHANIN for compensatory damages, you must also determine if TEVA is liable for punitive damages.

YES X NO ___

6. If you found BAXTER is liable to HENRY CHANIN or to LORRAINE CHANIN for compensatory damages, you must also determine if BAXTER is liable for punitive damages.

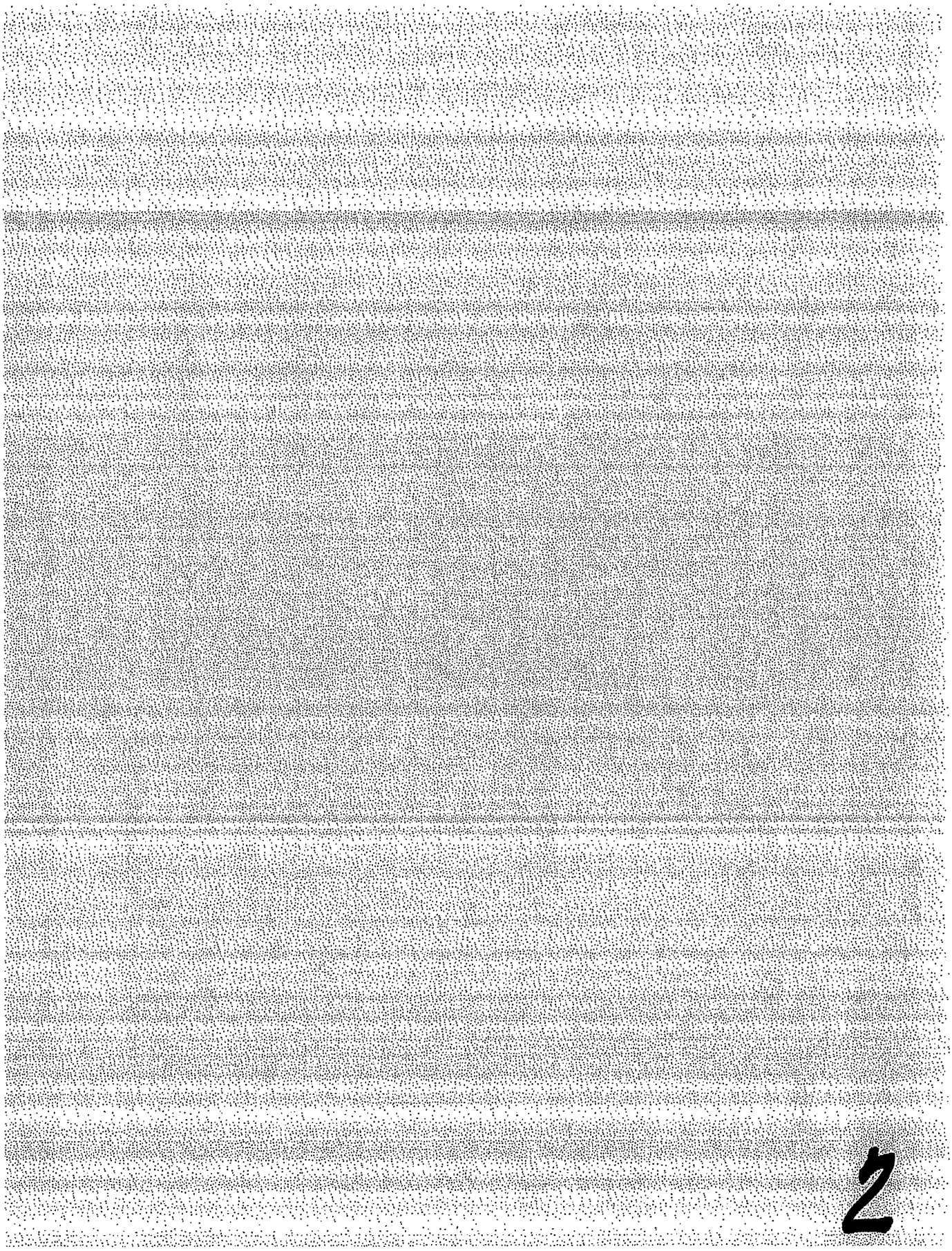
YES X NO ___

HENRY CHANIN COMPENSATORY DAMAGES $ 3.25 million

LORRAINE CHANIN COMPENSATORY DAMAGES $ 1.85 million

DATED this 5th day of May, 2010.

(FOREPERSON)



FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT

MAY 07 2010

BY, _____ TERI BRAZGELMANN DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

HENRY CHANIN and LORRAINE CHANIN, husband and wife

Plaintiffs,

vs.

TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., a Delaware Corporation; SICOR, INC., a Delaware Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware Corporation

Defendants.

CASE NO.: A571172
DEPT.NO.: X

SPECIAL VERDICT

We, the jury in the above entitled action, assess the amount of punitive damages as follows:

Punitive Damages Against TEVA $ 356,000,000

Punitive Damages Against BAXTER $ 144,000,000

DATED this 1st day of May, 2010.

FOREPERSON

EXHIBIT 6

Electronically Filed
11/16/2011 02:59:08 PM

CLERK OF THE COURT

JGJV
ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
ARTEMUS H. HAM, ESQ.
Nevada Bar No. 7001
MAINOR EGLET
400 South Fourth Street, Suite 600
Las Vegas, NV 89101
(702) 450-5400
Attorneys for Plaintiff Anne Arnold

WILLIAM S. KEMP, ESQ.
Nevada Bar No. 1205
KEMP JONES & COULTHARD LLP
3800 Howard Hughes Parkway, 17th Floor
Las Vegas, NV 89169
(702) 385-6000
Attorney for Plaintiffs, Sacks and Devito

MAINOR EGLET

DISTRICT COURT
CLARK COUNTY, NEVADA

RICHARD C. SACKS, individually Plaintiff, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, BAXTER HEALTHCARE CORPORATION, a Delaware Corporation. Defendants.	CASE NO.: A572315 DEPT. NO.: XXVIII **JUDGMENT UPON THE JURY VERDICT**
ANNE ARNOLD and JAMES ARNOLD, individually and as husband and wife Plaintiffs, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES. INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, BAXTER HEALTHCARE CORPORATION, a Delaware Corporation; Defendants.	CASE NO.: A576071 DEPT. NO.: XXVIII

☐ Voluntary Dis	☐ Stip Dis	☐ Sum Jdgmt	FINAL D
☐ Involuntary (stat) Dis	☐ Stip Jdgmt	☐ Non-Jury Trial	☐ Time
☐ Jdgmt on Arb Award	☐ Default Jdgmt	☒ Jury Trial	☐ Disn
☐ Mtn to Dis (by deft)	☐ Transferred		☐ Judg

11/7/11 (28)

ANTHONY V. DEVITO and DONNA JEAN DEVITO, individually and as husband and wife, Plaintiffs, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, MCKESSON CORPORATION, a Delaware Corporation. Defendants.	CASE NO.: A583058 DEPT. NO.: XXVIII

JUDGMENT UPON THE JURY VERDICT

This action came on for trial before the Court and the jury, the Honorable Ronald J. Israel, District Judge, presiding, and the issues having been duly tried and the jury having duly rendered their verdict[1] and also special verdict[2],

IT IS ORDERED AND ADJUDGED that Plaintiffs, RICHARD SACKS, ANNE ARNOLD and JAMES ARNOLD, ANTHONY V. DEVITO and DONNA JEAN DEVITO, have and recover of the Defendants, TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., a Delaware Corporation, SICOR, INC., a Delaware Corporation, BAXTER HEALTHCARE CORPORATION, a Delaware Corporation, and MCKESSON CORPORATION, a Delaware Corporation, the following sums:

COMPENSATORY DAMAGES FOR RICHARD SACKS:

Richard Sacks against TEVA & BAXTER	$ 5,000,000.00
Total Compensatory Damages for Richard Sacks:	**$ 5,000,000.00**

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiff's compensatory damages in the amount of Five Million 00/100 Dollars ($5,000,000.00), shall bear prejudgment interest in accordance with *Lee v. Ball, 116 P.3d 64*, (2005) at the rate of 5.25% per annum from the date of

[1] Exhibit 1, Verdict
[2] Exhibit 2, Special Verdict

MAINOR EGLET

service of the Summons and Complaint on Baxter Healthcare Corporation on September 29, 2008, and Sicor Pharmaceuticals, Inc. on January 20, 2009 and through November 9, 2011 as follows:

PREJUDGMENT INTEREST FOR RICHARD SACKS:

09/29/08 through 11/09/11 = $ 816,986.30
(1136 days x $719.17 per day)

COMPENSATORY DAMAGES FOR ANNE ARNOLD AND JAMES ARNOLD:

Anne Arnold against TEVA & BAXTER	$ 8,500,000.00
James Arnold against TEVA & BAXTER	$ 900,000.00
Total Compensatory Damages for Anne and James Arnold:	**$ 9,400,000.00**

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' compensatory damages in the amount of Nine Million Four Hundred Thousand and 00/100 Dollars ($9,400,000.00), shall bear prejudgment interest in accordance with *Lee v. Ball, 116 P.3d 64*, (2005) at the rate of 5.25% per annum from the date of service of the Summons and Complaint on Baxter Healthcare Corporation on December 23, 2008, and Sicor Pharmaceuticals, Inc. on January 16, 2009 and through November 9, 2011 as follows:

PREJUDGMENT INTEREST FOR ANNE ARNOLD AND JAMES ARNOLD:

12/23/08 through 11/09/11 = $ 1,421,009.58
(1051 days x $1,352.05 per day)

MAINOR EGLET

COMPENSATORY DAMAGES FOR ANTHONY DEVITO AND DONNA JEAN DEVITO:

Anthony Devito against TEVA & MCKESSON	$ 5,000,000.00
Donna Jean Devito against TEVA & MCKESSON	$ 700,000.00
Total Compensatory Damages for Anne and James Arnold:	**$ 5,700,000.00**

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' compensatory damages in the amount of Five Million Seven Hundred Thousand and 00/100 Dollars ($5,700,000.00), shall bear prejudgment interest in accordance with *Lee v. Ball, 116 P.3d 64*, (2005) at the rate of 5.25% per annum from the date of service of the Summons and Complaint on McKesson Corporation on March 5, 2009, and Sicor Pharmaceuticals, Inc. on March 7, 2009 and through November 9, 2011 as follows :

PREJUDGMENT INTEREST FOR ANTHONY DEVITO AND DONNA JEAN DEVITO:

03/05/09 through 11/09/11 =	$ 802,645.89
(979 days x $819.86 per day)	

PUNITIVE DAMAGES:

Richard Sacks, Anne Arnold, James Arnold, Anthony Devito and Donna Jean Devito against TEVA:	$ 89,375,000.00
Richard Sacks, Anne Arnold and James Arnold Against BAXTER:	$ 55,250,000.00
Anthony Devito and Donna Jean Devito against McKESSON	$ 17,875,000.00
Total Punitive Damages:	**$ 162,500,000.00**

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' punitive damages in the amount of One Hundred Sixty Two Million, Five Hundred Thousand and 00/100 Dollars ($162,500,000.00), shall bear postjudgment interest in accordance with *Lee v. Ball, 116 P.3d 64*,

(2005) at the rate of 5.25% per annum from the time of entry of judgment until satisfied as follows:

POSTJUDGMENT INTEREST:

$23,373.28 per day

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs may be awarded their costs of the action, the amount of which to be determined by the Court.

NOW, THEREFORE, Judgment Upon the Verdict in favor of Plaintiffs, RICHARD SACKS, ANNE ARNOLD and JAMES ARNOLD, ANTHONY V. DEVITO and DONNA JEAN DEVITO, is hereby given for One Hundred Eighty Five Million, Six Hundred Forty Thousand Six Hundred Forty One and 77/100 Dollars (**$185,640,641.77**) against Defendants which shall bear post judgment interest at the current rate of 5.25% or $26,701.73 per day, until satisfied.

DATED this 16 day of November, 2011.

DISTRICT COURT JUDGE

JV

Respectfully Submitted by:

Dated this 9th day of November, 2011.

ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
ARTEMUS W. HAM, ESQ.
Nevada Bar No. 7001
400 South Fourth Street, Suite 600
Las Vegas, NV 89101
Attorneys for Plaintiffs

WILLIAM S. KEMP, ESQ.
Nevada Bar No. 1205
KEMP JONES & COULTHARD LLP
3800 Howard Hughes Parkway, 17th Floor
Las Vegas, NV 89169
Attorney for Plaintiffs

EXHIBIT "1"

ORIGINAL

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT
OCT 0 6 2011
643pm
BY, KATHY KLEIN, DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

RICHARD C. SACKS, individually Plaintiff, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, BAXTER HEALTHCARE CORPORATION, a Delaware Corporation. Defendants.	CASE NO.: A572315 DEPT. NO.: XXVIII
ANNE ARNOLD and JAMES ARNOLD, individually and as husband and wife Plaintiffs, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, BAXTER HEALTHCARE CORPORATION, a Delaware Corporation; Defendants.	CASE NO.: A576071 DEPT. NO.: XXVIII
ANTHONY V. DEVITO and DONNA JEAN DEVITO, individually and as husband and wife, Plaintiffs, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, MCKESSON CORPORATION, a Delaware Corporation. Defendants.	CASE NO.: A583058 DEPT. NO.: XXVIII

VERDICT

We, the jury in the above-entitled action, return the following verdict:

Question No. 1: Is TEVA liable to ANNE ARNOLD for any of the following claims?

a. Duty to monitor

YES X NO _____

b. Defective product design

YES _____ NO X

c. Failure to send Dear Doctor letter

YES X NO _____

d. Breach of the implied warranty of fitness for particular purpose

YES X NO _____

Question No. 2: Is BAXTER liable to ANNE ARNOLD for any of the following claims?

a. Defective product design

YES _____ NO X

b. Failure to send Dear Doctor letter

YES X NO _____

c. Breach of the implied warranty of fitness for particular purpose

YES X NO _____

Question No. 3: If you find TEVA is liable to ANNE ARNOLD, is TEVA also liable to JAMES ARNOLD for loss of consortium?

YES X NO _____

Question No. 4: If you find BAXTER is liable to ANNE ARNOLD, is BAXTER also liable to JAMES ARNOLD for loss of consortium?

YES X NO _____

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Question No. 5: Is TEVA liable to ANTHONY DEVITO for any of the following claims?

a. Duty to monitor

YES X NO _____

b. Defective product design

YES _____ NO X

c. Failure to send Dear Doctor letter

YES X NO _____

d. Breach of the implied warranty of fitness for particular purpose

YES X NO _____

Question No. 6: Is MCKESSON liable to ANTHONY DEVITO for any of the following claims?

a. Defective product design

YES _____ NO X

b. Failure to send Dear Doctor letter

YES X NO _____

c. Breach of the implied warranty of fitness for particular purpose

YES X NO _____

Question No. 7: If you find TEVA is liable to ANTHONY DEVITO, is TEVA also liable to DONNA DEVITO for loss of consortium?

YES X NO _____

Question No. 8: If you find MCKESSON is liable to ANTHONY DEVITO, is MCKESSON also liable to DONNA DEVITO for loss of consortium?

YES X NO _____

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Question No. 9: Is TEVA liable to RICHARD SACKS for any of the following claims?

a. Duty to monitor

YES X NO ____

b. Defective product design

YES ____ NO X

c. Failure to send Dear Doctor letter

YES X NO ____

d. Breach of the implied warranty of fitness for particular purpose

YES X NO ____

Question No. 10: Is BAXTER liable to RICHARD SACKS for any of the following claims?

a. Defective product design

YES ____ NO X

b. Failure to send Dear Doctor letter

YES X NO ____

c. Breach of the implied warranty of fitness for particular purpose

YES X NO ____

Question No. 11: Do you find that any of the Plaintiffs have suffered damages as a result of any Defendants' conduct? If so, please state the damages, if any:

ANNE ARNOLD COMPENSATORY DAMAGES $ 8,500,000

JAMES ARNOLD COMPENSATORY DAMAGES $ 900,000

ANTHONY DEVITO COMPENSATORY DAMAGES $ 5,000,000

DONNA DEVITO COMPENSATORY DAMAGES $ 400,000

RICHARD SACKS COMPENSATORY DAMAGES $ 5,000,000

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Question No. 12: If you found that TEVA is liable to RICHARD SACKS, ANNE ARNOLD and/or ANTHONY DEVITO for compensatory damages, is TEVA also liable for punitive damages?

YES X NO _____

Question No. 13: If you found that BAXTER is liable to ANNE ARNOLD and/or RICHARD SACKS for compensatory damages, is BAXTER also liable for punitive damages?

YES X NO _____

Question No. 14: If you found that MCKESSON is liable to ANTHONY DEVITO for compensatory damages, is MCKESSON also liable for punitive damages?

YES X NO _____

DATED this 10th day of October, 2011.

Jerry L. Foster
FOREPERSON

EXHIBIT "2"

ORIGINAL

DISTRICT COURT

CLARK COUNTY, NEVADA

RICHARD C. SACKS, individually Plaintiff, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, BAXTER HEALTHCARE CORPORATION, a Delaware Corporation. Defendants.	CASE NO.: A572315 DEPT. NO.: XXVIII
ANNE ARNOLD and JAMES ARNOLD, individually and as husband and wife Plaintiffs, vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation. BAXTER HEALTHCARE CORPORATION, a Delaware Corporation; Defendants.	CASE NO.: A576071 DEPT. NO.: XXVIII
ANTHONY V. DEVITO and DONNA JEAN DEVITO, individually and as husband and wife, Plaintiffs. vs. SICOR, INC., a Delaware Corporation; TEVA PARENTERAL MEDICINES, INC., formerly known as SICOR PHARMACEUTICALS, INC., A Delaware Corporation, MCKESSON CORPORATION, a Delaware Corporation. Defendants.	CASE NO.: A583058 DEPT. NO.: XXVIII

SPECIAL VERDICT

We, the jury in the above-entitled action, assess the amount of punitive damages as follows:

Punitive Damages TEVA $89,375,000

Punitive Damages BAXTER $55,250,000

Punitive Damages MCKESSON $17,875,000

DATED this 10th day of October, 2011.

FOREPERSON

EXHIBIT 7

CLERK OF THE COURT

JUJV

EDWARD M. BERNSTEIN, ESQ.
Nevada Bar #1642
PATTI S. WISE, ESQ.
Nevada Bar #5624
EDWARD M. BERNSTEIN & ASSOCIATES
500 South Fourth Street
Las Vegas, Nevada 89101
Telephone: (702) 384-4000
Facsimile: (702) 385-4640

RICHARD H. FRIEDMAN, ESQ.
rfriedman@friedmanrubin.com
LINCOLN D. SIELER, ESQ.
lsieler@ friedmanrubin.com
Admitted Pro Hac Vice
FRIEDMAN | RUBIN
1126 Highland Avenue
Bremerton, WA 98337
Telephone: (360) 782-4300

Attomeys for Plaintiffs

DISTRICT COURT

CLARK COUNTY NEVADA

MICHAEL WASHINGTON and JOSEPHINE WASHINGTON, Plaintiffs, vs. TEVA PARENTERAL MEDICINES, INC.; SICOR, INC.; BAXTER HEALTHCARE CORPORATION, Defendants.	CASE NO. A558164 DEPT NO. XV

JUDGMENT UPON THE JURY VERDICT

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

This action came on for trial before the Court and the jury, the Honorable Abbi Silver, District Judge, presiding, and the issues having been duly tried and the jury having duly rendered their verdict[1].

IT IS ORDERED AND ADJUDGED that Plaintiffs, MICHAEL WASHINGTON and JOSEPHINE WASHINGTON, have and recover of the Defendants, TEVA PARENTERAL MEDICINES, INC. (hereinafter "TEVA"), SICOR, INC. (hereinafter "SICOR"), and BAXTER HEALTHCARE CORPORATION (hereinafter "BAXTER"), jointly and severally the following sums:

COMPENSATORY DAMAGES:

Michael Washington against TEVA, SICOR and BAXTER	$ 7,000,000.00
Josephine Washington against TEVA, SICOR and BAXTER	$ 7,000,000.00

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiff MICHAEL WASHINGTON have and recover of Defendants TEVA and SICOR, jointly and severally, the following sum as Punitive Damages:

PUNITIVE DAMAGES:

Michael Washington against TEVA and SICOR	$ 60,000,000.00

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiff MICHAEL WASHINGTON have and recover of Defendant BAXTER the following sum as Punitive Damages:

PUNITIVE DAMAGES:

Michael Washington against BAXTER	$ 30,000,000.00

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[1] *See* Special Verdict Forms attached as Exhibit "1".

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

IT IS FURTHER ORDERED AND ADJUDGED that this Judgment Upon the Verdict shall bear postjudgment interest as provided by NRS 17.130 from the date of entry of judgment until satisfied.

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs shall be awarded their costs of the action jointly and severally against the Defendants, the amount of which is to be determined by the Court upon Plaintiffs' Memorandum of Costs, to be filed within five (5) days of entry of this Judgment Upon the Verdict. Plaintiffs may also bring any motion for prejudgment interest and attorneys' fees pursuant to NRCP 68 and NRS 17.115 within ten (10) days of notice of entry of this Judgment.

NOW, THEREFORE, Judgment Upon the Verdict in favor of Plaintiff MICHAEL WASHINGTON, jointly and severally against TEVA, SICOR and BAXTER is hereby given for **Seven Million and 00/100 Dollars ($7,000,000.00)**, plus costs.

In addition, Judgment Upon the Verdict in favor of Plaintiff JOSEPHINE WASHINGTON, jointly and severally against TEVA, SICOR and BAXTER is hereby given for **Seven Million and 00/100 Dollars ($7,000,000.00)**, plus costs.

In addition, Judgment Upon the Verdict in favor of Plaintiff MICHAEL WASHINGTON, jointly and severally against TEVA and SICOR is hereby given for **Sixty Million and 00/100 Dollars ($60,000,000.00).**

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EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

In addition, Judgment Upon the Verdict in favor of Plaintiff MICHAEL WASHINGTON against BAXTER is hereby given for **Thirty Million and 00/100 Dollars ($30,000,000.00).**

DATED this 19th day of October, 2011.

DISTRICT COURT JUDGE

Respectfully Submitted by:

EDWARD M. BERNSTEIN & ASSOCIATES

BY: _____

PATTI S. WISE, ESQ.
Nevada Bar #5624
500 South Fourth Street
Las Vegas, Nevada 89101
Telephone: (702) 384-4000
Facsimile: (702) 385-4640
Attorneys for Plaintiffs WASHINGTON

A558164

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

EXHIBIT 1

EXHIBIT 1

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT
3:30 PM
OCT 10 2011
BY JENNIFER KIMMEL, DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

MICHAEL WASHINGTON and JOSEPHINE WASHINGTON, Plaintiffs, v. SICOR PHARMACEUTICALS, INC., et al., Defendants.	CASE NO. A558164 DEPT. NO. XV **SPECIAL VERDICT FORM**

08A558164
SJV
Special Jury Verdict
1546432

3

DISTRICT COURT

CLARK COUNTY, NEVADA

MICHAEL WASHINGTON and JOSEPHINE WASHINGTON, Plaintiffs, v. SICOR PHARMACEUTICALS, INC., et al., Defendants.	CASE NO. A558164 DEPT. NO. XV

Special Verdict

We the Jury in the above-entitled action find the following Special Verdict on the questions submitted to us:

1. Is Teva Parenteral Medicines, Inc. liable to Michael Washington for the following claims, if any:

   a. Negligence

   Yes ✓ No____

   b. Strict Liability for Defective Design of 50ml Propofol vial

   Yes ✓ No____

2. Is Baxter Healthcare Corporation liable to Michael Washington for the following claims, if any:

   a. Negligence

   Yes ✓ No____

   b. Strict Liability for Defective Design of 50ml Propofol vial

   Yes ✓ No____

3. If you find Teva Parenteral Medicines, Inc. is liable to Michael Washington, you must also determine if Teva Parenteral Medicines, Inc. is liable to Josephine Washington for loss of consortium.

   Yes ✓ No____

4. If you find Baxter Healthcare Corporation is liable to Michael Washington, you must also determine if Baxter Healthcare Corporation is liable to Josephine Washington for loss of consortium.

Yes ✓ No ___

5. What amount of damages, if any, do you find was sustained by:

Michael Washington compensatory damages $ 7million

Josephine Washington compensatory damages $ 7million

6. If you found that Teva Parenteral Medicines, Inc. is liable to Michael Washington, you must also determine if Teva Parenteral Medicines Inc. is liable for punitive damages:

Yes ✓ No ___

7. If you found that Baxter Healthcare Corporation is liable to Michael Washington for compensatory damages you must also determine if Baxter Healthcare Corporation is liable for punitive damages:

Yes ✓ No ___

Dated this 10th day of October, 2011.

FOREPERSON

DISTRICT COURT

CLARK COUNTY, NEVADA

*****

FILED IN OPEN COURT
STEVEN D. GRIERSON
CLERK OF THE COURT
2:16 P.M.
OCT 12 2011
BY, JENNIFER KIMMEL, DEPUTY

MICHAEL WASHINGTON and JOSEPHINE WASHINGTON,

Plaintiffs,

vs.

TEVA PARENTERAL MEDICINES, INC.; SICOR, INC.; BAXTER HEALTHCARE CORPORATION,

Defendants.

CASE NO. A558164
DEPT NO. XV

03A558164
SVF
Special Verdict Form
1861266

SPECIAL VERDICT

We, the jury in the above entitled action, award punitive damages to plaintiff Michael Washington as follows:

Punitive Damages Against Teva Parenteral Medicines, Inc.: $ 60 million

Punitive Damages Against Baxter Healthcare Corporation: $ 30 million

DATED this 12 day of October, 2011.

FOREPERSON

EXHIBIT 8

ORIGINAL

Electronically Filed
07/28/2011 04:46:02 PM

CLERK OF THE COURT

ORDR
Judge Ronald J. Israel
Eighth Judicial District Court
Department XXVIII
Regional Justice Center
200 Lewis Avenue
Las Vegas, Nevada 89155
(702)671-3631
(702)366-1407 Facsimile

DISTRICT COURT

CLARK COUNTY, NEVADA

RICHARD C. SACKS, individually, et al, Plaintiff(s), vs. ENDOSCOPY CENTER OF SOUTHERN NEVADA, LLC, et al. Defendant(s), And All Related/Consolidated Matters.	Case No. 08A572315 (LEAD) CONSOLIDATED with 08A576071 and 09A583058 DEPT. NO. XXVIII ***ELECTRONIC FILING CASE***

DECISION AND ORDER: PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT ON PREEMPTION DEFENSE FOR DEAR DOCTOR LETTER LIABILITY ... PRODUCT DEFENDANTS' PRE-TRIAL MOTION #4, MOTION FOR SUMMARY JUDGMENT ON GROUNDS OF FEDERAL PREEMPTION ON ORDER SHORTENING TIME

This case arises out of the transmission of Hepatitis C from patient to patient at various endoscopy clinics in Las Vegas. Causation of the transmission is highly contested by the parties; however, the main theories are either the transmission by means of "double dipping" regarding the use of Propofol as an anesthetic in the procedures or improper cleaning and sterilization of the medical equipment at the time of the procedures. This motion is regarding summary judgment based on *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

RECEIVED
JUL 28 2011
CLERK OF THE COURT

The *Mensing* Decision was announced by the United States Supreme Court (herein after "Supreme Court") approximately two (2) weeks ago. The parties agree that the Supreme Court has precluded claims against a generic drug manufacturer for failure to warn as long as the generic warning is equivalent to the brand name warning. The Supreme Court based their Decision on the fact that federal law preempts state law. Plaintiffs have agreed that a failure to warn claim is no longer at issue; however, they argue that the *Mensing* Decision does not preclude a "Dear Doctor letter" that is consistent with the federal warning label.

In the *Mensing* Decision the parties did not dispute that state law required the manufacturers to use a different and safer label. In the *Sacks* case, Plaintiffs claim the state law does not require a stronger warning and, therefore, preemption does not apply. If state law is not preempted, then the generic manufacturers should have issued a "Dear Doctor letter" reiterating the single-use warning on the Propofol bottle. The *Mensing* Court states, "What is in dispute is whether, and to what extent, generic manufacturers may change their labels after initial FDA approval." The Plaintiffs in *Mensing* clearly seek a stronger warning than was previously approved and, therefore, the Supreme Court ruled that the federal law prevented them from changing the label and the claims were dismissed.

The facts in the *Sacks* case differ, in that, first of all, we are not talking about the medicine contained in the bottle but, in fact, the means of accessing the medicine in the bottle; i.e., the single- or multi-use container. In the *Mensing* case at Page 8, Part 2, the Court states, "The FDA argues that "Dear Doctor letters" qualify as "labeling" ... Thus any such letters must be "consistent with and not contrary to [the drugs] approved labeling." Once again, the United States Supreme Court draws a distinction between additional and/or stronger warnings that were the subject of the *Mensing* case and not the subject of the *Sacks* case.

The Supreme Court in *Mensing* for a third time states at Page 12, "...State law imposed on

the Manufacturers a duty to attach a safer label (emphasis added) to their generic metoclopramide." This, once again, is not the same as we have in the *Sacks* case at issue. The Supreme Court states at Page 13, "The question for "impossibility" is whether the private party could independently do under federal law what state law requires of it." In the *Sacks* case it is clear the allegations are that the generic manufacturer could have done a "Dear Doctor letter" that does not violate federal law. The issue as to whether or not the "Dear Doctor letter" would have made a difference is a question of fact to be determined by the Jury and, therefore, Defendants' Motion For Summary Judgment is DENIED.

Defendants also seek to lump the Second and Third Causes of Action regarding design defect and breach of implied warranty of fitness for a particular purpose together and base their argument on the *Mensing* case. If the Supreme Court had intended to preclude all tort claims against generic manufacturers then they would have said so. This is certainly not the interpretation by this Court, and, therefore their arguments regarding the other Causes of Action are DENIED.

Plaintiffs' Motion For Summary Judgment is also DENIED as there are questions of fact to be determined by the Jury at the time of trial.

DATED AND DONE this 28 day of July, 2011.

DISTRICT JUDGE RONALD J. ISRAEL

EXHIBIT 9

EXHIBIT 9

ODM
EDWARD M. BERNSTEIN, ESQ.
Nevada Bar #1642
PATTI S. WISE, ESQ.
Nevada Bar #5624
GARY W. CALL, ESQ.
Nevada Bar #6922
EDWARD M. BERNSTEIN & ASSOCIATES
500 South Fourth Street
Las Vegas, Nevada 89101
Telephone: (702) 384-4000
Facsimile: (702) 385-4640

RICHARD H. FRIEDMAN, ESQ.
Admitted Pro Hac Vice
LINCOLN D. SIELER, ESQ.
Admitted Pro Hac Vice
FRIEDMAN RUBIN
1126 Highland Avenue
Bremerton, Washington 98337
Telephone: (360) 782-4300

Attorneys for Plaintiffs

DISTRICT COURT
CLARK COUNTY, NEVADA

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MICHAEL WASHINGTON and JOSEPHINE WASHINGTON, Plaintiffs, vs. TEVA PARENTERAL MEDICINES, INC.; SICOR, INC.; BAXTER HEALTHCARE CORPORATION, Defendants.	CASE NO. A558164 DEPT NO. XV

ORDER DENYING PRODUCT DEFENDANTS' MOTION IN LIMINE NO. 9 TO EXCLUDE TESTIMONY, REFERENCES OR ARGUMENTS THAT CHALLENGE THE SUFFICIENCY OR ADEQUACY OF THE PROPOFOL WARNINGS FEDERAL LAW COMPELLED PRODUCT DEFENDANTS TO USE

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS, NEVADA 89101
(702) 240-0000

Product Defendants' Motion in Limine No. 9 to Exclude Testimony, References or Arguments that Challenge the Sufficiency or Adequacy of the Propofol Warnings Federal Law Compelled Product Defendants to Use, having come before this Hon. Court on August 17, 2011, Plaintiffs Michael and Josephine Washington, appearing by and through their attorneys of record, Richard Friedman, Esq., Lincoln Sieler, Esq., of the law firm Friedman | Rubin, and Patti S. Wise, Esq., of the law firm of Edward M. Bernstein and Associates, and Defendants Teva Parenteral Medicines, Inc., formerly known as Sicor Pharmaceuticals, Inc., Sicor, Inc., and Baxter Healthcare Corporation, appearing by and through their attorneys of record, Glenn Kerner, Esq. of the law firm Goodwin Procter, Michael Stoberski, Esq., of the law firm Olson, Cannon, Gormley & Desruisseaux, and Michael Shumsky, Esq., of the law firm Kirkland & Ellis LLP, the Court having considered argument of counsel and the papers and pleadings on file, the Court finds:

Pliva, Inc. v. Mensing, 79 USLW 4606, 564 U.S. --, 2011 WL 247290 (June 23, 2011), held that plaintiffs are foreclosed from bringing claims against a generic pharmaceutical manufacturer based on failure to use a better warning due to preemption. The United States Supreme Court did not rule that a generic warning the FDA previously approved is "sufficient" or "adequate" as a matter of law. Thus, evidence relating to alleged flaws or defects in the existing labels is relevant to Plaintiffs' claims for design defect, negligence claims and the Defendants' intervening superseding cause defense.

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EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

Accordingly, **IT IS HEREBY ORDERED** that, Product Defendants' Motion in Limine No. 9 to Exclude Testimony, References or Argument that Challenges the Sufficiency of Adequacy of the Propofol Warnings Federal Law Compelled Product Defendants to Use **IS DENIED** as that is a question for the Jury to determine.

DATED this 8 day of September, 2011.

DISTRICT COURT JUDGE Abbi Silver

Submitted by:

EDWARD M. BERNSTEIN & ASSOCIATES

BY: _____

PATTI S. WISE, ESQ.
Nevada Bar #5624
500 South Fourth Street
Las Vegas, Nevada 89101
Telephone: (702) 384-4000
Facsimile: (702) 385-4640
Attorneys for Plaintiffs WASHINGTON

A558164

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

EXHIBIT 10

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OGM
EDWARD M. BERNSTEIN, ESQ.
Nevada Bar #1642
PATTI S. WISE, ESQ.
Nevada Bar #5624
GARY W. CALL, ESQ.
Nevada Bar #6922
EDWARD M. BERNSTEIN & ASSOCIATES
500 South Fourth Street
Las Vegas, Nevada 89101
Telephone: (702) 384-4000
Facsimile: (702) 385-4640

RICHARD H. FRIEDMAN, ESQ.
Admitted Pro Hac Vice
LINCOLN D. SIELER, ESQ.
Admitted Pro Hac Vice
FRIEDMAN RUBIN
1126 Highland Avenue
Bremerton, Washington 98337
Telephone: (360) 782-4300

Attorneys for Plaintiffs

DISTRICT COURT

CLARK COUNTY, NEVADA

*****

MICHAEL WASHINGTON and JOSEPHINE WASHINGTON, Plaintiffs, vs. TEVA PARENTERAL MEDICINES, INC.; SICOR, INC.; BAXTER HEALTHCARE CORPORATION, Defendants.	CASE NO. A558164 DEPT NO. XV

ORDER GRANTING IN PART AND DENYING IN PART PRODUCT DEFENDANTS' PRE-TRIAL MOTION #7 TO ADMIT EVIDENCE AND EXPERT TESTIMONY OF THE HATCH-WAXMAN ACT, FDA REGULATIONS, PHARMACEUTICAL INDUSTRY PRACTICE, AND PRODUCT DEFENDANTS' COMPLIANCE THEREWITH FOR PROPOFOL

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

THIS COURT, having entertained Product Defendants' Pretrial Motion #7 to Admit Evidence and Expert Testimony of the Hatch-Waxman Act, FDA Regulations, Pharmaceutical Industry Practice, and Product Defendants' Compliance Therewith for Propofol on August 17, 2011, with Plaintiffs Michael and Josephine Washington, appearing by and through their attorneys of record, Richard Friedman, Esq., Lincoln Sieler, Esq., of the law firm Friedman | Rubin, and Patti S. Wise, Esq., of the law firm of Edward M. Bernstein and Associates, and Defendants Teva Parenteral Medicines, Inc., formerly known as Sicor Pharmaceuticals, Inc., Sicor, Inc., and Baxter Healthcare Corporation, appearing by and through their attorneys of record, Glenn Kerner, Esq. of the law firm Goodwin Procter, Michael Shumsky, Esq. of the law firm of Kirkland & Ellis, LLP, and Michael Stoberski, Esq., of the law firm Olson, Cannon, Gormley & Desruisseaux, the Court having considered argument of counsel and the papers and pleadings on file, the Court finds:

Subject to the Product Defendants' specific offers of proof and the proper laying of a foundation, the Product Defendants shall be generally entitled to offer evidence regarding the following: (1) Propofol is a generic version of the brand pharmaceutical product Diprivan; (2) Propofol and its label are FDA approved; (3) Propofol and Diprivan have the same language for their labels and warnings; (4) by law Propofol cannot unilaterally change its warnings and labels; (5) Propofol was in compliance with FDA requirements at the time of Michael Washington's treatment; (6) the FDA did not prohibit the sale of 50 mL vials to ambulatory surgical centers and, in fact, approved the Product Defendants' labeling and products as suitable for use during outpatient surgical procedures; and (7) other manufacturers used the same warnings.

However, the Court also finds the following: (1) Federal law does not place the responsibility solely upon brand name pharmaceuticals to monitor medical literature and to disseminate warnings to health care providers; (149:22-24) (2) *Mensing* does not prohibit generic

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000

manufacturers from sending "Dear Doctor" letters so long as they do not alter or change the existing warnings; and (3) the parties may not present evidence as to industry customs regarding what a medical professional would expect a marketing representative to do or not to do regarding the use of the product.

The court declined to rule that any specific evidence was admissible and said it would wait to rule on that until more specifics were provided. See. p. 167:19-25, 169:25-170:1, 171:5-11, 172:1-15, 190:15-193:22.

DATED this 20 day of Sept., 2011.

DISTRICT COURT JUDGE Abbi Silver

Submitted by:

EDWARD M. BERNSTEIN & ASSOCIATES

BY: _____

PATTI S. WISE, ESQ.
Nevada Bar #5624
500 South Fourth Street
Las Vegas, Nevada 89101
Telephone: (702) 384-4000
Facsimile: (702) 385-4640
Attorneys for Plaintiffs WASHINGTON

A558164

EDWARD M. BERNSTEIN & ASSOCIATES
ATTORNEYS AT LAW
500 SO. FOURTH ST.
LAS VEGAS,
NEVADA 89101
(702) 240-0000