LernerDavid
INTELLECTUAL PROPERTY LAW

Lerner David Littenberg
Krumholz & Mentlik LLP
600 South Avenue West
Westfield NJ 07090
908 654 5000 main
lernerdavid.com

Nichole M. Valeyko
908.518.6327
nvaleyko@lernerdavid.com

April 20, 2018

(Electronically Filed)
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P O Box 1450
Alexandria, VA 22313-1450

Inter Partes Review IPR2018-00943 (Patent No. 7,919,499)
Exhibit Cover Letter Per 37 C.F.R. § 42.6(e)(4)(ii)

Dear Patent Trial and Appeal Board:

This transmittal letter identifies Exhibits 1001-1060, being filed concurrently with the present Petition for *Inter Partes* Review. Pursuant to 37 C.F.R. § 42.6(e)(4)(ii), the Certificate of Service attached to the end of the Petition for *Inter Partes* Review filed herewith, incorporates Exhibits 1001-1060, as listed below:

Exhibit #	Reference
1001	U.S. Patent No. 7,919,499 ("the '499 Patent")
1002	U.S. Serial Number 11/083,167, Office Action, May 5, 2009
1003	Serial No. 11/083,167, Declaration Under 37 C.F.R. § 1.132 of Elliot Ehrich (undated)
1004	U.S. Serial Number 11/083,167, Amendment and Response, Oct. 5, 2009
1005	U.S. Serial Number 11/083,167, Office Action, Jan. 6, 2010
1006	U.S. Serial Number 11/083,167, Amendment and Response, Apr. 5, 2010
1007	U.S. Serial Number 11/083,167, Final Rejection, July 20, 2010
1008	U.S. Serial Number 11/083,167, Amendment After Final, Oct. 20, 2010
1009	U.S. Serial Number 11/083,167, Notice of Allowance, Dec. 1, 2010
1010	Sandra D. Comer *et al.*, *Depot naltrexone: long-lasting antagonism of the effects of heroin in humans*, 159(4) Psychopharmacology (Feb. 2002), at 351-360
1011	Henry R. Kranzler *et al.*, *Sustained-Release Naltrexone for Alcoholism Treatment: A Preliminary Study*, 22(5) Alcoholism: Clinical and Experimental Research (Aug. 1998), at 1074-79
1012	C.N. Chiang *et al.*, *Clinical Evaluation of A Naltrexone Sustained-Release Preparation*, 16 Drug & Alcohol Dependence (1985), at 1-8
1013	T.N. Alim *et al.*, *Tolerability Study of A Depot Form of Naltrexone Substance Abusers*, Problems of Drug Dependence, 1994: Proceedings of the 56th Annual Scientific Meeting, The College on Problems of Drug Dependence, Inc., Vol. II: Abstracts, National Institute on Drug Abuse Research Monograph 153 (1995), at 253
1014	U.S. Patent No. 7,157,102 ("the '102 Patent" or "Nuwayser")

Exhibit #	Reference
1015	U.S. Patent No. 6,306,425 ("Tice")
1016	U.S. Securities and Exchange Commission, *FORM 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended March 31, 2002*. Alkermes, Inc. (July 2002)
1017	U.S. Trademark Application Serial Number 76/271,990, Allegation of Use of a Mark & specimen of the mark as used in commerce, Aug. 15, 2002 ("Vivitrex Specimen" or "Specimen")
1018	U.S. Patent No. 6,264,987 ("the '987 Patent" or "Wright")
1019	S.J. Heishman *et al., Safety And Pharmacokinetics of a New Formulation of Depot Naltrexone*, Problems of Drug Dependence, 1993: Proceedings of the 55th Annual Scientific Meeting, The College on Problems of Drug Dependence, Inc., Volume II: Abstracts, National Institute on Drug Abuse Research Monograph 141 (1994)
1020	U.S. Patent and Trademark Office, 1265(2) *Official Gazette of the United States Patent and Trademark Office*, Trademarks, Dec. 10, 2002
1021	Intentionally left blank
1022	Stewart B. Leavitt, PhD, ed., *Evidence for the Efficacy of Naltrexone in the Treatment of Alcohol Dependence (Alcoholism)*, Addition Treatment Forum Naltrexone Clinical Update (2002 Clinco Communications, Inc.), at 1-8
1023	ReVia, *Physicians' Desk Reference* 936-938 (53rd ed. 1999) ("PDR")
1024	U.S. Patent No. 4,882,335 ("Sinclair")
1025	Chiang *et al., Kinetics of a naltrexone sustained-release preparation*, 36(5) Clin. Pharmacol. Ther. (Nov. 1984), at 704-08 "Kinetic of a naltrexone sustained-release preparation."
1026	Reuning *et al., Pharmacokinetic Quantitation of Naltrexone Release From Several Sustained-Release Delivery Systems*, Naltrexone: Research Monograph 28 (R. E. Willette and G. Barnett, eds. National Institute on Drug Abuse 1980)
1027	Appeal Brief, Application No. 13/871,534, Oct. 19, 2015
1028	G. Rubio *et al., Naltrexone Versus Acamprosate: One Year Follow-Up of Alcohol Dependence Treatment*, 36(5) Alcohol & Alcoholism (2001), at 419-425
1029	Intentionally left blank
1030	Declaration of Kinam Park Ph.D in Support of *Inter Partes* Review of U.S. Patent No. 7,919,499
1031	Curriculum Vita of Kinam Park
1032	U.S. Provisional Application No. 60/564,542
1033	Manit Srisurapanont & Ngamwong Jarusuraisin, *Naltrexone for the treatment of alcoholism: a meta-analysis of randomized controlled trials*, 8 Int'l J. of Neuropsychopharmacology (2005), at 267-280
1034	Bouza Carmen *et al., Efficacy and safety of naltrexone and acamprosate in the treatment of alcohol dependence: a systematic review*, 99(7) Addiction (July 2004), at 811-828

Exhibit #	Reference
1035	J.S. Hopkins *et al.*, *Naltrexone and Acamprosate Meta-Anaylsis of Two Medical Treatments for Alcoholism*, 26(5) Alcoholism Clinical and Experimental Research, 2002 Scientific Meeting of the Research Society on Alcoholism and the 11th Congress of the Int'l Society for Biomedical Research on Alcoholism, June 28-July 3, 2002, San Francisco, California (Suppl. May 2002)
1036	*Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, Product Details for NDA 018932, REVIA (NALTREXONE HYDROCHLORIDE) 50MG
1037	*Bioequivalence*, Center for Drug Evaluation and Research, Application Number: 75-434, Naltrexone Hydrochloride Tablets, Eon Labs Manufacturing, Inc., at 1-8
1038	Synopsis, Naltrexone HCl, ALZA Corporation (Nov. 3, 2003)
1039	In-hwan Baek *et al.*, *Evaluation of the Bioequivalence of Two Brands of Naltrexone 50 mg Tablet in Healthy Volunteers*, 16(1) Kor. J. Clin. Pharm. (2006), at 69-74
1040	TREXAN™, *Physicians' Desk Reference* 936-938 (46 ed. 1992) ("PDR"), at 937-939
1041	*Trademark Manual of Examining Procedure (TMEP)* (3rd ed. Jan. 2002), at 100-5 to 100-11
1042	*Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, NALTREXONE (VIVITROL) FOR SUSPENSION, EXTENDED RELEASE 380MG/VIAL
1043	General Notices and Requirements, USP 32/NF 27 (2009) at 8
1044	Bertil Abrahamsson and Anna-Lena Ungell, *Biopharmaceutical support in formulation development*:*A Practical Guide from Candidate Drug Selection to Commercial Dosage Form*, Pharmaceutical Preformulation and Formulation (Mark Gibson ed., Interpharm/CRC) (2004), 239-291, at 262
1045	Guidance for Industry. Bioavailability and Bioequivalence Studies for Orally Administered Products—General Considerations. FDA CDER (March 2003)
1046	Riddle *et al.*, *Anxiolytics, adrenergic agents, and naltrexone*, 38(5) J. Am. Acad. Child. Adolesc. Psychiatry, 546-556 (May 1999)
1047	Food and Drug Administration, *FDA PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE MEETING VIVITROL® (naltrexone for extended-release injectable suspension)*, NDA 21-897 (Sept. 16 2010)
1048	Intentionally left blank
1049	Rothenberg *et al.*, *Behavioral naltrexone therapy: an integrated treatment for opiate dependence*, 23 J. of Substance Abuse Treatment (2002), at 351-360
1050	B.A. Johnson, *Naltrexone long-acting formulation in the treatment of alcohol dependence*, 3(5) Ther. Clin. Risk Manag., 741-749 (2007), at 742.

Exhibit #	Reference
1051	Food and Drug Administration, Guidance for Industry, *Exposure-response relationships – study design, data analysis, and regulatory applications*, FDA CDER (April 2003)
1052	Food and Drug Administration, Guidance for Industry, *Statistical approaches to establishing bioequivalence*, FDA CDER (April 2003)
1053	Schenker *et al.*, *Antecedent liver disease and drug toxicity*, 31 J. of Hepatology 1098-1105 (1999)
1054	Résumé of Mike Ramstack, as obtained from LinkedIn
1055	Résumé of Richard Reuning, as obtained from LinkedIn
1056	Résumé of Steve Wright, as obtained from LinkedIn
1057	U.S. Patent No. 3,332,950
1058	Filing Details for Alkermes Inc. 10-K dated July 1, 2002 from the Security and Exchange Commission's EDGAR Online Filing System
1059	WayBack Machine capture of Security and Exchange Commission's Information Page regarding the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR), June 6, 2002
1060	WayBack Machine capture of Security and Exchange Commission's Regulator Overview of the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR), June 6, 2002

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP

Nichole M. Valeyko
Registration No. 55,832

/dmf