IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VELOXIS PHARMACEUTICALS, INC.,	)	
	)	
	)	
Plaintiff,	)	
	)	
-v.-	)	Civil Action No. 14-cv-2126 (RBW)
	)	
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
	)	
	)	
Defendants.	)	

JOINT APPENDIX OF ADMINISTRATIVE RECORD

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March 17, 2015

TAB	DATE	DOCUMENT DESCRIPTION	BATES RANGE	DESIGNATION
1	1/12/15	Letter from R. Albrecht to Veloxis, response to request for final approval of NDA 206406	FDA 00001 – FDA 00004	Confidential
2	1/12/15	Letter from R. Albrecht to Veloxis, General Advice Letter re: NDA 206406	FDA 00005 – FDA 00057	Confidential
3	1/12/15	Memorandum from J. Sitlani and R. Albrecht to NDA 206406 file (Memo to File)	FDA 00058 – FDA 00116	Confidential
4	2006	HU Meier-Kriesche, S Li, RW Gruessner, et al., 2006, Immunosuppression: Evolution in Practice and Trends, 1994-2004, Am J Transplant, 6 (5 Pt 2):1111-1131	FDA 00117 – FDA 00137	
5	12/31/12	Hardinger, KL, DC Brennan, and CL Klein, July 2013, Selection of Induction Therapy in Kidney Transplantation, Transpl Int, 26(7):662-672	FDA 00138 – FDA 00148	
6	4/23/14	WH Lim, J Eris, J Kanellis, et al., Sept. 2014, A Systematic Review of Conversion from Calcineurin Inhibitor to Mammalian Target of Rapamycin Inhibitors for Maintenance Immunosuppression in Kidney Transplant Recipients, Am J Transplant,14(9):2106-2119	FDA 00149 – FDA 00162	
7	8/27/11	Holdaas, H, L Rostaing, D Serón, et al., Aug. 27, 2011, Conversion of Long-Term Kidney Transplant Recipients from Calcineurin Inhibitor Therapy to Everolimus: A Randomized, Multicenter, 24-Month Study, Transplantation, 92(4):410-418	FDA 00163 – FDA 00171	
8	9/25/03	Budde, K, J Curtis, G Knoll, et al., Enteric-Coated Mycophenolate Sodium Can Be Safely Administered in Maintenance Renal Transplant Patients: Results of a 1-Year Study, Am J Transplant; 4(2):237-243	FDA 00172 – FDA 00178	
9	12/4/12	Scientific Registry of Transplant Recipients 2011 Annual Report, Table 5.6	FDA 00179 – FDA 00181	
10	7/1/14	FDA Draft Guidance on Tacrolimus for Extended Release Capsule/Oral	FDA 00182 – FDA 00187	
11	9/4/13	Approved Product Labeling for Prograf (NDA 050708)	FDA 00188 – FDA 00230	
12	N/A	Orange Book Entries for Prograf (NDA 050708)	FDA 00311 – FDA 00320	

TAB	DATE	DOCUMENT DESCRIPTION	BATES RANGE	DESIGNATION
13	2/1/14	Approved Product Labeling for Astagraf XL (NDA 204096)	FDA 00321 – FDA 00357	
14	7/19/13 & 6/19/13	Clinical Review for Astagraf XL (NDA 204096)	FDA 00358 – FDA 00548	Confidential
15	7/19/13	Division Director Summary Review of Astagraf XL (NDA 204096)	FDA 00549 – FDA 00573	Confidential
16	1/29/29	Letter from E. Essig, Astellas to FDA/CDER requesting withdrawal of NDA 050811	FDA 00873	Confidential
17	2/10/09	Letter from R. Albrecht, FDA/DSPTP to E. Essig, Astellas granting withdrawal of NDA 050811	FDA 00874 – FDA 00875	Confidential
18	10/30/09	Letter from J. Meyer, FDA/DTOP to E. Essig, Astellas, meeting minutes from 9/29/2009 meeting re support for kidney transplant indication for Astagraf XL (formerly NDA 050811)	FDA 00882 – FDA 00898	Confidential
19	2/28/12	Letter from R. Albrecht, FDA/DSPTP to E. Essig, Astellas, meeting minutes re 1/31/2012 pre-NDA meeting for Astagraf XL	FDA 00899 – FDA 00907	Confidential
20	7/19/13	Letter from R. Albrecht to Astellas Pharma re: NDA 204096 Astagraf XL Approval	FDA 00911 – FDA 00917	Confidential
21	2/12/14	Letter from R. Albrecht to Astellas Pharma re: Supplemental Approval NDA 204096/S- 001	FDA 00918 – FDA 00920	Confidential
22	2/28/14	Letter from R. Albrecht to Astellas Pharma re: Supplemental Approval NDA 204096/S- 002	FDA 00921 – FDA 00926	Confidential
23	7/19/13	Astagraf XL (NDA 204096) Exclusivity Summary	FDA 01082 – FDA 01089	
24	N/A	Orange Book Entries for Astagraf XL (NDA 204096) and Exclusivity Codes	FDA 01090 – FDA 01101	
25	8/5/10	Letter from R. Albrecht, FDA/DSPTP to R. Guido, LifeCycle, regarding Special Protocol Agreement for LCP-Tacro (IND 75,250)	FDA 01102 – FDA 01107	Confidential
26	5/1/02	FDA's guidance for industry, Special Protocol Assessment	FDA 01108 – FDA 01121	
27	9/25/14	Clinical Review for Envarsus XR (NDA 206406)	FDA 01122 – FDA 01300	Confidential

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28	7/23/14	Budde, K, S Bunnapradist, JM Grinyo, et al., Dec. 20 14, Novel Once-Daily ER Tacrolimus (LCPT) Versus Twice-Daily Tacrolimus in De Novo Kidney Transplants: One-Year Results of Phase III, Double-Blind, Randomized Trial, Am J Transplant, 14(12):2796-2806.	FDA 01301 – FDA 01311	
29	9/12/14	Letter from M. Pritza, Astellas to R. Albrecht, FDA/DTOP, request for clarification of Astagraf XL's 3-year exclusivity	FDA 01417 – FDA 01419	Confidential
30	10/17/14	Letter from CDER Exclusivity Board, FDA to M. Pritza, Astellas, re: Exclusivity for Astagraf XL (NDA 204096)	FDA 01420 – FDA 01507	Confidential
31	10/27/14	Letter from P. Safir, Covington & Burling on behalf of Astellas to CDER Exclusivity Board, FDA, re: Exclusivity for Astagraf XL (NDA 204096)	FDA 01508 – FDA 01533	Confidential
32	10/27/14	Letter from L. Almoza, FDA/DTOP to M. McGuinness, Veloxis, Information Request - Exclusivity	FDA 01534 – FDA 01536	Confidential
33	10/29/14	Letter from M. McGuinness, Veloxis to L. Almoza, FDA/DTOP, Envarsus XR Response to Information Request - Exclusivity	FDA 01537 – FDA 01539	Confidential
34	10/30/14	Memorandum from R. Albrecht, FDA/DTOP and J. Sitlani to NDA 206406, Tentative Approval for Envarsus XR	FDA 01540 – FDA 01543	Confidential
35	10/30/14	Letter from R. Albrecht, FDA/DTOP to M. McGuinness, Veloxis, Tentative Approval for Envarsus XR (NDA 206406)	FDA 01544 – FDA 01584	Confidential
36	10/31/14	Email from J. Bragg, Skadden on behalf of Veloxis to E. Dickinson FDA/OCC requesting meeting	FDA 01585 – FDA 01587	Confidential
37	11/6/14	FDA Public Calendar Notice, Veloxis meeting with E. Dickinson, FDA/OCC	FDA 01588 – FDA 01591	
38	11/6/14	Veloxis Presentation Slides to FDA, NDA 206406	FDA 01592 – FDA 01622	Confidential
39	11/10/14	Letter from R. Albrecht, FDA/DTOP to M. McGuinness, Veloxis, General Advice/Information Request (NDA 206406)	FDA 01623 – FDA 01625	Confidential
40	11/14/14	Letter from M. McGuinness, Veloxis to L. Almoza, FDA/DTOP, Envarsus XR Request for Final Approval (Veloxis Submission)	FDA 01626 – FDA 01643	Confidential

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41	11/14/14	Veloxis Submission Exhibit 1: Declaration of NKF Saffer	FDA 01644 – FDA 01644	Confidential
42	11/14/14	Veloxis Submission Exhibit 2: Declaration of Roy Bloom, MD	FDA 01645 – FDA 01677	Confidential
43	11/14/14	Veloxis Submission Exhibit 3: Review Article. Barraclough, Once- Versus Twice- Daily Tacroliums	FDA 01678 – FDA 01694	Confidential
44	11/14/14	Veloxis Submission Exhibit 4: Presentation Slides	FDA 01695 – FDA 01725	Confidential
45	11/14/14	Veloxis Submission Exhibit 5: Article in American Journal of Transplantation. Meier-Kruescge, Lack of Improvement in Renal Allograft Survival Despite a Marked Decrease in Acute Rejection Rates Over the Most Recent Era	FDA 01726 – FDA 01731	Confidential
46	11/14/14	Veloxis Submission Exhibit 6: Article in Clinincal and Translational Research. De Jonge, Reduced C0 Concentrations and Increased Dose Requirements in Renal Allograft Recipients Converted to the Novel Once-Daily Tacrolimus Formulation	FDA 01732 – FDA 01738	Confidential
47	12/2/14	Letter from M. McGuinness, Veloxis to L. Almoza, FDA/DTOP, Supplement to Request for Final Approval for Envarsus XR	FDA 01739 – FDA 01742	Confidential
48	12/5/14	Envarsus XR Teleconference Meeting Minutes	FDA 01748 – FDA 01750	Confidential
49	12/8/14	Letter from W. Polvino, Veloxis to L. Almoza, FDA/DTOP, Envarsus XR Supplement to Request for Final Approval, Declaration of Anthony Langone	FDA 01751 – FDA 01758	Confidential
50	12/12/14	Letter from W. Polvino, Veloxis to L. Almoza, FDA/DTOP, Envarsus XR Supplement to Request for Final Approval	FDA 01759 – FDA 01761	Confidential
51	12/12/14	Letter from R. Albrecht, FDA/DTOP to W. Polvino, Veloxis, General Advice re: Envarsus XR	FDA 01762 – FDA 01766	Confidential
52	12/16/14	Letter from W. Polvino, Veloxis to L. Almoza, FDA/DTOP, Supplement to Request for Final Approval	FDA 01768 – FDA 01770	Confidential
53	10/14/03	Letter from J. Woodcock, FDA/CDER to K. Sanzo, J. Chasnow, S. Lawton, et al., 505(b)2 Citizen Petition Petition Response (Docket Nos. 2001P-0323, 2002P-0047, and 20030408)	FDA 01771 – FDA 01808	Confidential
54	1/8/15	CDER Exclusivity Board Memo re: Astagraf XL 3-year Exclusivity	FDA 01897 – FDA 01902	Confidential

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55	10/8/13	ClinicalTrials.gov: "Crossover Study to Compare PKs of Once Daily [ER] Tacrolimus Tablets to Generic Tacrolimus Capsules Twice Daily"	FDA 01903 – FDA 01906	
56	10/1/99	Draft Guidance for Industry, Applications Covered by Section 505(b)(2)	FDA 01941 – FDA 01955	
57	9/18/13	Letter from J. Woodcock, CDER/FDA to D. Clissold, Hyman, Phelps & McNamara, P.C., Suboxone Citizen Petition Response Docket Nos. FDA-2011-P-0869 and FDA-2013-P0995	FDA 01956 – FDA 01966	
58	1/1/14	Patent and Exclusivity Terms, Approved Drug Products with Therapeutic Equivalence Evaluations, "The Orange Book," 34th Ed.	FDA 01972 – FDA 02033	
59	5/25/11	Letter from J. Woodcock, FDA to G. Veron, Mutual Pharmaceuticals, Response to Colcrys Citizen Petition (Docket No. FDA- 2010-P-0614)	FDA 02034 – FDA 02060	
60	8/1/12	Astellas Pharma Exclusivity Request for Astagraf XL (NDA 204096)	FDA 02068 – FDA 02082	
61	10/31/14	Reuters, *Zogenix and Purdue Pharma Exchange Waivers of Regulatory Exclusivity for Extended-Release Hydrocodone Products*	FDA 02133 – FDA 02136	
62	11/20/14	CBS, *FDA approves new, hard-to-abuse hydrocodone painkiller*	FDA 02151 – FDA 02152	
63	10/24/96	Exclusivity Summary for Combivent (NDA 020291)	FDA 02153 – FDA 02158	Confidential
64	10/24/96	Approved Product Labeling for Combivent (NDA 020291)	FDA 02159 – FDA 02175	Confidential
65	10/3/96	Division Director Review for Combivent (NDA 020291)	FDA 02176 – FDA 02179	Confidential
66	5/27/99	Division Director Review for Duoneb (NDA 020950)	FDA 02180 – FDA 02182	Confidential
67	5/7/10	Memorandum from S. Hertz, FDA/Division of Anesthesia and Analgesia Products to K. Webber, FDA/Office of Generic Drugs re: Scope of Three-year Exclusivity Granted to Ryzolt (tramadol hydrochloride) extended release tablets	FDA 02183 – FDA 02188	Confidential
68	5/25/11	FDA Response to Citizen Petition re Colchicine GL Veron (Docket No. FDA-2010- P-0614)	FDA 02198 – FDA 02224	
69	12/13/13	Currently Approved Labeling for Ritalin (NDA 010187) and Ritalin SR (NDA 018029)	FDA 02297 – FDA 02314	

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70	4/3/01	Approval Package for Metadate CD (NDA 021259)	FDA 02315 – FDA 02569	Confidential
71	8/1/00	Approval Package for Concerta (NDA 021121)	FDA 02570 – FDA 02904	Confidential
72	2/28/00	Approval Package for Androgel 1% (NDA 021015)	FDA 02905 – FDA 03229	Confidential
73	10/31/02	Approval Package for Testim (NDA 021454)	FDA 03230 – FDA 03500	Confidential
74	8/26/09	Other documents related to Testim, including Aug 26, 2009 Letter from CDRH to Auxilium Pharmaceuticals, Inc. (Docket No. FDA 2009-P-0123), Testim Supervisory Pharmacologist Memo to the NDA (Jan. 21, 2003), Testim Exclusivity Determination Checklist, and Jan. 17, 20013 letter from CDER to Auxilium	FDA 03501 – FDA 03517	Confidential
75	12/29/10	Approval Package for Fortesta (NDA 021463)	FDA 04145 – FDA 05006	Confidential
76	4/29/11	Approval Package for Androgel 1.62% (NDA 022309)	FDA 05041 – FDA 06163	Confidential