Warning Letters 2015

These letters are supplied by the CDER Freedom of Electronic Information Office. This page only covers Office of Prescription Drug Promotion (formerly Division of Drug Marketing, Advertising and Communications) and CDER Headquarters Warning Letters.

- **Office of Prescription Drug Promotion Letters**
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For District Office Warning Letters see the Main FDA FOI Warning Letters Page. Some of the letters have been redacted or edited to remove confidential information. Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the letter. If you wish to obtain available additional information on the current status of an issue in a particular warning letter or notice of violation on this website, please contact the Agency or the recipient of the letter directly. Inquiries to FDA should be sent to:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane, Rockville, MD 20857

Instructions for how to submit an FOI request can be found on the FDA FOI Page.

Office of Prescription Drug Promotion

Company/Individual	Product/Issue	Issue Date

Duchesnay, Inc. • Warning Letter (PDF) • Promotional Material (PDF)	NDA 021876 DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets, for oral use	8/7/2015
ECR Pharmaceuticals, a wholly owned subsidiary of Valeant Pharmaceuticals International • Warning Letter (PDF) • Promotional Material (PDF)	ANDA 077273 TussiCaps(hydrocodone polistirex and chlorpheniramine polistirex) Extended-release Capsules CII	7/27/2015
ASCEND Therapeutics US, LLC • Untitled letter (PDF) • Promotional Material (PDF)	EstroGel® 0.06% (estradiol gel) for topical use	6/23/2015
Actavis Laboratories UT, Inc. (formerly Watson Laboratories, Inc.) • Untitled Letter (PDF) • Promotional Material (PDF)	NDA 022206 RAPAFLO® (silodosin) Capsule for oral use	5/19/2015
Oak Pharmaceuticals, Inc. • Untitled Letter (PDF) • Promotional Material (PDF)	ANDA 083246 Nembutal Sodium Solution (pentobarbital sodium injection, USP) CII	5/14/2015
Otsuka Pharmaceutical Development & Commercialization, Inc. • Untitled Letter (PDF) • Promotional Material (PDF)	NDA 021436 ABILIFY (aripiprazole) Tablets	4/17/2015
Discovery Laboratories • Untitled Letter (PDF) • Promotional Material (PDF)	NDA 021746 Surfaxin (lucinactant) Intratracheal Suspension	3/5/2015
Gary W. Small, MD Semel Institute for Neuroscience & Human Behavior, UCLA Taumark.com • Untitled Letter (PDF) • Promotional Material (PDF)	(F-18) FDDNP	2/20/2015
Luitpold Pharmaceuticals, Inc. • Untitled Letter (PDF)	NDA 203565 Injectafer (ferric carboxymaltose injection)	1/29/2015

Office of Compliance/Immediate Office

Company/Individual	Product/Issue	Issue Date
Vista Pharmaceuticals, Ltd. (WARNING LETTER)	Failure to pay GDUFA fees	6/22/2015
Sharon Bio-Medicine Limited (WARNING LETTER)	Failure to pay GDUFA fees	6/22/2015
Syntho Pharmaceuticals (WARNING LETTER)	Failure to pay GDUFA fees	6/22/2015
Wuxi Kaili Pharmaceutical Company (WARNING LETTER)	Failure to pay GDUFA fees	6/22/2015
RemedyRepack Inc. (WARNING LETTER)	Colchicine Tablet (NDC 49349-061)	3/31/2015
Rebel Distributors Corp. (WARNING LETTER)	Cimetidine 300 mg tablet (NDC 21695-531), Cimetidine 400 mg tablet (NDC 21695-532), Digoxin 0.125 mg tablet (NDC 21695-678) and Hydrocodone Barbiturate and Acetaminophen 10mg/ 500 mg tablet (NDC 21695-273)	3/15/2015
Iso-Tex Diagnostics, Inc (WARNING LETTER)	Volumex (Albumin Iodinated I-131 Serum) 0.025 mCi/mL	3/2/2015
Hemp Oil Care www.hempoilcare.com (WARNING LETTER)	“Cibdex Hemp CBD Complex Drops,” “Cibaderm Hemp Salve,” “Dixie Botanicals Dew Drops Hemp Oil Supplement,” “Hemp Honey 21% Cannabidiol Oil,” “Hemp Honey CBD Vape Oil,” and “Hemp Pure Vape E-Drops”	2/26/2015
Modern Herb Shop Inc. www.modernherbshop.com (WARNING LETTER)	“Bone Knitting Powder,” “Bu Zhong Yi Qi Wan | Central Chi Teapills,” “Burn Ointment | Ching Wan Hung Soothing Herbal Balm,” “Chuan Xin Lian,” “Huang Lian Su,” “San Huang San | Herbal Ice,” “Si Miao San Herb Extract Powder,” “Wu Yang Brand Pain Relieving Medicated Plaster,” “Yunnan Baiyao Capsules and Powder,” and “Zheng Gu Shui”	2/26/2015

Natural Organic Solutions www.purecbd.net and www.etsy.com/shop/PureCBD (WARNING LETTER)	"CBD Hemp Oil Treatment," "Hemp CBD (Cannabidiol) Extract Capsules," "CBD Extract Capsules Anti Anxiety Formula," and "High CBD Healing Salve"	2/26/2015
Infiniti Creations, Inc. www.curadermcream.com (redirected to: www.bec5creamdirect.com) (WARNING LETTER)	"Curaderm BEC 5 Cream" and "Tamanu Oil"	2/26/2015

Office of Manufacturing Quality

Company/Individual	Product/Issue	Issue Date
Zhejiang Hisun Pharmaceutical Co., Ltd. (WARNING LETTER)	CGMP/Active Pharmaceutical Ingredients (APIs)	12/31/2015
Cadila Healthcare Limited (WARNING LETTER)	CGMP/Active Pharmaceutical Ingredients (APIs)	12/23/2015
Sun Pharmaceuticals Industries Ltd. (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated	12/17/2015
Chan Yat Hing Medicine Factory (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated	12/15/2015
Dr. Reddy's Laboratories Limited (WARNING LETTER)	CGMP/Active Pharmaceutical Ingredients (APIs)	11/5/2015
Sandoz Private Limited (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated	10/22/2015
Unimark Remedies Ltd. (WARNING LETTER)	CGMP/Active Pharmaceutical Ingredients (APIs)	9/28/2015
Jaychem Industries, Inc. (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated	9/4/2015

Pan Drugs Limited (WARNING LETTER)	CGMP/Active Pharmaceutical Ingredients (APIs)	9/2/2015
Mylan Laboratories Limited (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated	8/6/2015
Sipra Labs Limited (WARNING LETTER)	regulations for testing finished pharmaceuticals and active pharmaceutical ingredients (APIs)	7/23/2015
Mahendra Chemicals (WARNING LETTER)	CGMP/Active Pharmaceutical Ingredients (APIs)	7/13/2015
Attix Pharmaceuticals (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated	6/22/2015
VUAB Pharma a.s. (WARNING LETTER)	CGMP/Finished Pharmaceuticals/Adulterated 320-15-10	5/27/15
Yunnan Hande Bio-Tech. Co. Ltd. (WARNING LETTER)	manufacture of active pharmaceutical ingredients (APIs)	4/6/2015
Hospira S.p.A. (WARNING LETTER)	regulations for finished pharmaceuticals	3/31/2015
Novacyl (Thailand) Ltd. (WARNING LETTER)	manufacture of active pharmaceutical ingredients (APIs)	2/27/2015
Cadila Pharmaceuticals Limited (WARNING LETTER)	manufacture of active pharmaceutical ingredients (APIs)	2/25/2015
Micro Labs Limited (WARNING LETTER)	regulations for finished pharmaceuticals	1/9/2015
Apotex Research Private Limited (WARNING LETTER)	regulations for finished pharmaceuticals	1/30/2015

Office of Scientific Investigations

Company/Individual	Product/Issue	Issue Date
Bernard A. Michlin, M.D. (WARNING LETTER)	Clinical Investigator	7/13/2015
Howard M. Gross, M.D.	Clinical Investigator	6/29/15

(WARNING LETTER)		
AB Science (WARNING LETTER)	Sponsor	6/16/15
Binh Bui Nguyen, M.D. (WARNING LETTER)	Clinical Investigator	5/4/2015
CXL-USA, LLC (WARNING LETTER)	Sponsor	4/1/2015

Office of Drug Security, Integrity and Recalls

Company/Individual	Product/Issue	Issue Date
Rx Partners (WARNING LETTER)	Unlawful Sale of Unapproved and Misbranded Drug Products to United States consumers over the Internet	6/8/2015
Meds India LTD (WARNING LETTER)	Unlawful Sale of Unapproved and Misbranded Drug Products to United States consumers over the Internet	6/8/2015

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Contact FDA