

MISSING FDA WARNING LETTERS

The following pages were captured directly from the FDA website on 11-June-2009. The URL link used was

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM055773>

Note that the April 2009 table listing all the warning letters issued during that month DO NOT contain any description or links to 5 letters that were originally sent to the following companies on April 2, 2009:

1. Biogen Idec
2. Cephalon
3. Forest Laboratories
4. GlaxoSmithKline
5. Sanofi-Aventis US

This was explained in the following Pharma Marketing Blog post:

“Missing Warning Letters Prove that FDA is an Internet Dunce!” (<http://tinyurl.com/lo8lbd>)

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Guidance, Compliance & Regulatory Information

Enforcement Activities by FDA

Warning Letters and Notice of Violation Letters to Pharmaceutical Companies

Warning Letters 2009

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Warning Letters 2009

2009 Warning Letters and Untitled Letters to Pharmaceutical Companies

These letters, sorted by month, are supplied by the CDER Freedom of Electronic Information Office. This page only covers Division of Drug Marketing and Communications and Headquarters Warning Letters. 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. Click on the links in each month to view the letters in Adobe Acrobat format. [\[more...\]](#)

May 2009

Product/Issue	Company/Individual	Division	Released	Posted
PerioChip (chlorhexidine gluconate) (Warning Letter) <ul style="list-style-type: none"> Promotional Material 	Dexcel Pharma Technologies Ltd.	Division of Drug Marketing, Advertising, and Communications	5/14/2009	5/19/2009
Spectracef (cefditoren pivoxil) Tablets (Warning Letter) <ul style="list-style-type: none"> Promotional Material 	Cornerstone Therapeutics, Inc.	Division of Drug Marketing, Advertising, and Communications	5/4/2009	5/19/2009
ULTRAM ER (tramadol HCl) (Warning Letter)	Johnson & Johnson	Division of Drug Marketing, Advertising, and Communications	5/12/2009	5/19/2009

April 2009

Product/Issue	Company/Individual	Division	Released	Posted
Taxotere (docetaxel)	sanofi-aventis	Division of Drug Marketing, Advertising, and Communications	4/16/2009	5/13/2009
Clinical Investigation (Warning Letter)	Coast IRB	Division of Scientific Investigations	4/14/2009	4/14/2009
Site Inspection (Warning Letter)	Qingdao Jiulong Biopharmaceuticals Co. Ltd.	Division of Manufacturing and Product Quality	4/14/2009	4/16/2009
NDA 21-400 LEVITRA (vardenafil HCl) Tablets; NDA 21-676, 21-873, 22-045 YAZ (drospirenone and ethinyl estradiol) Tablets; NDA 21-225 Mirena (levonorgestrel-releasing intrauterine system) <ul style="list-style-type: none"> FDA/DDMAC letter Promotional Material 	Bayer Healthcare Pharmaceuticals, Inc.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009
	Johnson & Johnson	Division of Drug	4/2/2009	4/3/2009

NDA 21-976 PREZISTA (darunavir) Tablet <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Pharmaceutical Services	Marketing, Advertising, and Communications		
NDA 20-753 AROMASIN (exemestane) tablets; NDA 21-540 CADUET (amlodipine besylate/atorvastatin calcium) Tablets; NDA 21-928 CHANTIX® (varenicline) Tablets; NDA 21-228 Detrol LA (tolterodine tartrate) extended release capsules; NDA 21-446, 21-723, 21-724 LYRICA (pregabalin) Capsules; NDA 20-998, 21-156 CELEBREX (celecoxib) capsules <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Pfizer, Inc.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009
NDA 20-726 Femara (letrozole tablets); NDA 21-283 Diovan (valsartan) Tablets; NDA 21-990 Exforge (amlodipine and valsartan) Tablets; NDA 21-882 EXJADE (deferasirox) Tablets for Oral Suspension; NDA 21-588 GLEEVEC (imatinib mesylate) Tablets for Oral Use <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Novartis Pharmaceuticals Corp.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009
BLA 125085 Avastin (Bevacizumab); BLA 125156 LUCENTIS (ranibizumab injection); BLA 103705, 103737 RITUXAN (rituximab); BLA 103976 Xolair (Omalizumab) For Subcutaneous Use; BLA 103792 HERCEPTIN (trastuzumab); BLA 103532 Pulmozyme (dornase alfa) Inhalation Solution <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Genentech, Inc.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009
NDA 21-395 Spiriva HandiHaler (tiotropium bromide inhalation powder); NDA 20-579 Flomax (tamsulosin hydrochloride) Capsules; NDA 20-667 Mirapex (pramipexole dihydrochloride) Tablets <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Boehringer Ingelheim Pharmaceuticals, Inc.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009
NDA 21-995 JANUVIA (sitagliptin) Tablets; NDA 20-788 PROPECIA (finasteride) Tablets; NDA 20-829, 20-830,	Merck & Co., Inc.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009

21-409 SINGULAIR (montelukast sodium) granule; tablet, chewable; tablet, film coated; NDA 21-549 EMEND (aprepitant) Capsules <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 				
NDA 21-455, 21-858 BONIVA (ibandronate sodium) Tablets; BLA 103964 PEGASYS (peginterferon alfa-2a) for Injection; NDA 20-896 XELODA (capecitabine) Tablets <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Hoffman-LaRoche, Inc.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009
NDA 21-427, 21-733, 22-148 Cymbalta (duloxetine hydrochloride) Delayed-Release Capsules for Oral Use; NDA 20-815, 22-042 EVISTA (raloxifene hydrochloride) Tablets for Oral Use; NDA 20-509 Gemzar (gemcitabine HCl) for Injection <ul style="list-style-type: none"> ● FDA/DDMAC letter ● Promotional Material 	Eli Lilly and Co.	Division of Drug Marketing, Advertising, and Communications	4/2/2009	4/3/2009

March 2009

Product/Issue	Company/Individual	Division	Released	Posted
Morphine Sulfate Tablets, 15 mg & 30 mg; Morphine Sulfate Solution Immediate Release Concentrate, 20 mg/ml; Morphine Sulfate Solution Immediate Release Oral Solution, 20mg/5ml	Glenmark Generics Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Morphine Sulfate Solution Immediate Release Concentrate, 20 mg/ml; Hydromorphone HCl Tablets, 2mg and 4mg	Lannett Company, Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Morphine Sulfate Tablets, 15 mg & 30 mg; Morphine Sulfate Solution Concentrate, 20 mg/ml	Lehigh Valley Technologies Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Morphine Sulfate Concentrate Oral Solution 20mg/ml	Mallinckrodt Inc. Pharmaceuticals Group PDF version	Office of Compliance	3/30/2009	3/31/2009
Roxanol Oral Solution, 20 mg/ml; Roxicodone Tablets, 5 mg	Xanodyne Pharmaceuticals Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Morphine Sulfate Immediate Release	Physicians Total Care, Inc.	Office of Compliance	3/30/2009	3/31/2009

Tablets, 30 mg; Hydromorphone Tablets, 2 mg; Hydromorphone Hydrochloride Tablets 4 mg	PDF version			
Hydromorphone Hydrochloride Tablets, 2 mg & 4 mg	Roxane Laboratories, Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Roxanol Oral Solution, 20 mg/ml; Roxicodone Tablets, 5 mg	Boehringer Ingelheim Roxane Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Morphine Sulfate Solution Immediate Release 20mg/ml	Cody Laboratories, Inc. PDF version	Office of Compliance	3/30/2009	3/31/2009
Clinical Investigation (Warning Letter)	Charles J. Cote, M.D.	Division of Scientific Investigations	3/2/2009	3/3/2009
Clinical Investigation (Warning Letter)	Virendra Desai, M.D.	Division of Scientific Investigations	3/2/2009	3/5/2009
Clinical Investigation (Warning Letter)	Virendra Desai, M.D.	Manuel J. Quinones, M.D.	3/3/2009	3/5/2009

February 2009

Product/Issue	Company/Individual	Division	Released	Posted
Avodart (dutasteride) Soft Gelatin Capsules ● promotional material	GlaxoSmithKline	Division of Drug Marketing, Advertising, and Communications	2/18/2009	2/26/2009
Inspection of Pharmaceutical Manufacturing Facility (Warning Letter)	Barrie Levitt, M. D.	Division of Manufacturing & Product Quality	2/5/2009	2/5/2009
Letairis (ambrisentan)	Gilead Sciences, Inc.	Division of Drug Marketing, Advertising, and Communications	2/27/2009	3/5/2009

January 2009

Product/Issue	Company/Individual	Division	Released	Posted
Clinical Investigation (Warning Letter)	Nicola Spirtos, M.D	Division of Scientific Investigations	1/3/2009	1/22/2009
Depakote (divalproex sodium) ● promotional material	Abbott Laboratories	Division of Drug Marketing, Advertising, and Communications	1/22/2009	1/29/2009
Sanctura (trospium chloride) ● promotional material	Indevus Pharmaceuticals, Inc.	Division of Drug Marketing, Advertising, and Communications	1/27/2009	1/29/2009

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 (HF1-35)
5600 Fishers Lane, Rockville, MD 20857

Instructions for how to submit an FOI request can be found on the [FDA FOI Page](#).

The letters are arranged in chronological order by month. Click on the product name to view the letters in Adobe Acrobat (PDF) format.

Page Last Updated: 06/08/2009

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