Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 7, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Pfizer Inc. – RECALL [Drug]

AFFECTED PRODUCT: **Effexor XR® (venlafaxine HCl) 150 mg extended-release capsules 30 count, Effexor XR (venlafaxine HCl) 150 mg extended-release capsules 90 count, Greenstone LLC-branded Venlafaxine HC1 150 mg extended-release capsules 90 count.**

SUMMARY: **Unclassified Recall; The recall is due to a pharmacist report that one bottle of Pfizer's Effexor XR contained one capsule of Tikosyn® (dofetilide) 0.25mg in addition to the Effexor XR capsules.**

This recall is to the patient level and involves Pfizer lot numbers V130142 and V130140, which both expire in October 2015, and Greenstone lot number V130014, which expires in August 2015.

These products were distributed nationally to wholesalers, distributors, certain government agencies, patient assistance programs and retailers, such as pharmacies and hospitals. These direct customers are being notified by UPS next day mail, and Pfizer is arranging for the return of all recalled products.

SUGGESTED ACTION: **For consumer inquiry only. Patients with questions regarding the return of product should contact Stericycle at 1-888-345-0481 (Monday to Friday 8am to 5pm ET). Patients with questions regarding this recall can contact Pfizer Medical Information at 1-800-438-1985 (Monday to Thursday 9am to 8pm ET or Friday, 9am to 5pm ET).**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Pfizer Initiates Nationwide Voluntary Recall of Two Lots of Pfizer's Effexor XR® 150 Mg Extended-Release Capsules and One Lot of Greenstone's Venlafaxine HCl 150 Mg Extended-Release Capsules Due to the Possible Presence of Tikosyn® Capsules

Contact
Consumer:
1-888-345-0481
1-800-438-1985

Media:
MacKay Jimeson
1-212-733-2324

FOR IMMEDIATE RELEASE - March 6, 2014 - NEW YORK, NY – Pfizer Inc. is voluntarily recalling one lot of 30-count Effexor XR® (venlafaxine HCl) 150 mg extended-release capsules, one lot of 90-count Effexor XR (venlafaxine HCl) 150 mg extended-release capsules and one lot of 90-count Greenstone LLC-branded Venlafaxine HC1 150 mg extended-release capsules.

This action is being taken because of a pharmacist report that one bottle of Pfizer's Effexor XR contained one capsule of Tikosyn® (dofetilide) 0.25mg in addition to the Effexor XR capsules. Although Pfizer has not received any other such reports, these three lots are being voluntarily recalled as a precaution because they were packaged on the same line.

The use of Tikosyn by an Effexor XR/Venlafaxine HCl patient, where the contraindications and drug-drug interactions with Tikosyn have not been considered by the prescribing physician, could cause serious adverse health consequences that could be fatal.

While there is a very low probability that other bottles of Effexor XR contain a Tikosyn capsule, Pfizer has initiated this voluntary recall as a precaution.

Effexor XR is a prescription antidepressant indicated for the treatment of major depressive disorder, general anxiety disorder, social anxiety disorder, and panic disorder with or without agoraphobia. Tikosyn is a Class III (cardiac action potential duration prolonging) antiarrhythmic drug. It is used to treat irregular heartbeats (such as atrial fibrillation (AF) and atrial flutter (AFL)) and to maintain normal sinus rhythm (normal heartbeat) in patients with AF or AFL of greater than one week duration who have been converted to normal sinus rhythm.

This recall is to the patient level and involves Pfizer lot numbers V130142 and V130140, which both expire in October 2015, and Greenstone lot number V130014, which expires in August 2015.

These products were distributed nationally to wholesalers, distributors, certain government agencies, patient assistance programs and retailers, such as pharmacies and hospitals. These direct customers are being notified by UPS next day mail, and Pfizer is arranging for the return of all recalled products.

Wholesalers, distributors, government agencies, patient assistance programs and retailers with product that is being recalled should stop distribution and promptly return the product to Stericycle Inc. Please contact Stericycle at 1-888-345-0481 for instructions on returning product.

Pharmacists should immediately quarantine, discontinue distribution of and return all recalled lots of these products, as well as notify any of their customers to whom they distributed the products.

Patients with affected product should notify their physicians and/or return product to their pharmacies.

Patients with questions regarding the return of product should contact Stericycle at 1-888-345-0481 (Monday to Friday 8am to 5pm ET). Patients with questions regarding this recall can contact Pfizer Medical Information at 1-800-438-1985 (Monday to Thursday 9am to 8pm ET or Friday, 9am to 5pm ET).

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Tikosyn can cause serious side effects, including a type of abnormal heartbeat called Torsade de Pointes, which can lead to death. If an Effexor XR/Venlafaxine HCl patient thinks they may have mistakenly ingested a Tikosyn capsule, they should immediately contact their physician or hospital. Patients should also watch for signs of abnormal heartbeat, and inform their physician or hospital if they

- feel faint
- become dizzy, or
- have a fast heartbeat

Pfizer has responded rapidly to this situation to ensure the safety of patients who take our medicines. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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Pfizer Initiates Nationwide Voluntary Recall of Two Lots of Pfizer's Effexor XR® 150 Mg Extended-Release Capsules and One Lot of Greenstone's Venlafaxine HCl 150 Mg Extended-Release Capsules Due to the Possible Presence of Tikosyn® Capsules

Photo

Effexor XR / Venlafaxine HCl 150mg	Tikosyn 0.25mg
	
Encapsulated into #0E (closed length: 0.921 in +/- 0.012 in) opaque dark orange, locking type, elongated hard gelatin capsule shells	Encapsulated into #4 (closed length: 0.563 in +/- 0.012 in), peach/peach opaque, locking type, hard gelatin capsule shells

Time/Date: 11950400.pdf 1 11/17/11 11:30 AM

PAR No.	Component Number	Description
2011-0008677	11950400	Effexor

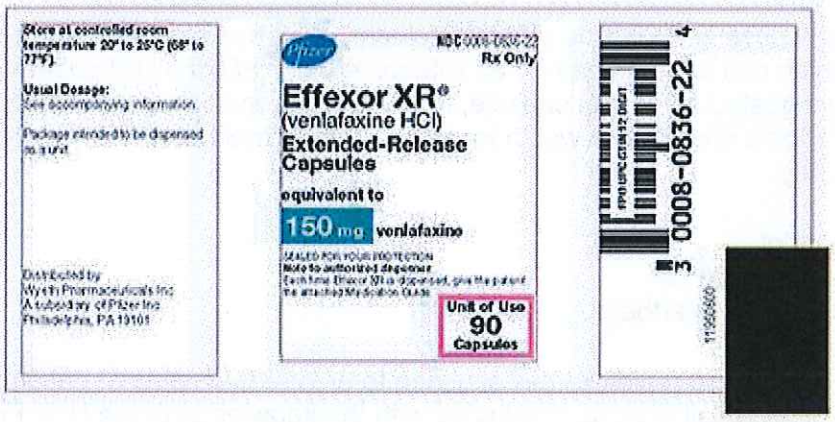
Dimensions	Drawing No.	Country	Item
1.56" x 4.75"	DWG-101357-00	US	IC Label

Additional Info:

Colors:

Color Bar Positions: Black, PMS 285, PMS 8282, PMS 363, Debo, 50% Varnish

PS N. Santana
QS J. Maury
QA H. Albizu



Time/Date: 11950600.pdf 1 12/8/11 3:30 PM

PAR No.	Component Number	Description
2011-0008677	11950600	Effexor

Dimensions	Drawing No.	Country	Item
4 3/4" x 2 1/4"	DWG-101080-00	US	IC Label

Additional Info:

Colors:

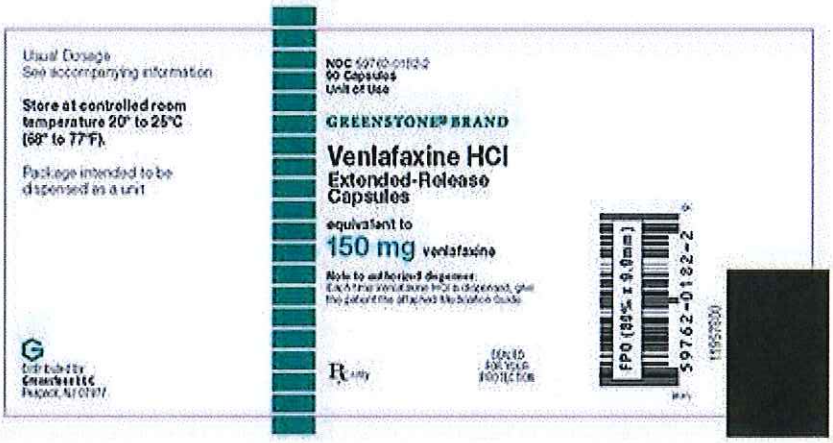
Color Bar Positions: Black, PMS 285, PMS 8282, PMS 813, Debo, 50% Varnish

PS N. Santana
QS J. Maury
QA H. Albizu

Pfizer PACKAGE DESIGN & DEVELOPMENT PHARMACEUTICAL PROMOTED PRODUCTS	COMPONENT: Pressure Sensitive Laser Coded Label	INSTRUCTIONS: PRINTING TEXT AREA : Indicated in grey on schematic above. VARNISH AREA Over all, Laser Box 50% varnish. DO NOT CHANGE LOCATION of Specification number and LOT & EXP. SPECIFICATION NUMBER: • 0.042" (3 pts) required space between pic number and laser box • 0.042" (3 pts) minimum space between bar code human readable and Specification number • Specification number font size must be 6 pts. Helvetica Medium Condensed.
PFIZER: DWG-101080-00	DESCRIPTION: 180cc - S&T (Barcode Position-option 2)	
	SIZE: 4-3/4" x 2-1/4" / DIE: N/A	
	APPROVED: [signature] DATE: 12/8/11	TEXT AREA / DIE LINE / 50% VARNISH

Pfizer PACKAGE DESIGN & DEVELOPMENT PHARMACEUTICAL PROMOTED PRODUCTS	COMPONENT: Pressure Sensitive Laser Coded Label DESCRIPTION: 180cc - S&T (Barcode Position-option 2) SIZE: 4-3/4" x 2-1/4" DIE: N/A APPROVAL DATE: Pfizer Confidential	INSTRUCTIONS: PRINTING TEXT AREA : indicated in grey on schematic above VARNISH AREA Over all Laser Box 50% varnish DO NOT CHANGE LOCATION of Specification number and LOT & EXP SPECIFICATION NUMBER: • 0.062" (3 pts) required space between pic number and laser box • 0.062" (3 pts) minimum space between bar code human readable and Specification number • Specification number font size must be 6 pts. Helvetica Medium Condensed TEXT AREA DIE LINE 50% VARNISH

Uncontrolled document when exported or printed



Time/Date: 11957800.pdf 1 9/9/11 2:56 PM

Pfizer PACKAGE DESIGN & DEVELOPMENT	PAR No.: 2011-0009040	Component Number: 11957800	Description: Venlafaxine 150mg 90ccount	
	Dimensions: 4.75" x 2.25"	Drawing No.: DWG-101080-00	Country: USA	Item: IC Label
Additional Info:	Colors: Black, PMS 8282, PMS 3288, Define, 50% Varnish		PS Norberto Santana GS Amal Abdalla QA José A. Guzmán	

Pfizer PACKAGE DESIGN & DEVELOPMENT PHARMACEUTICAL PROMOTED PRODUCTS	COMPONENT: Pressure Sensitive Laser Coded Label DESCRIPTION: 180cc - S&T (Barcode Position-option 2) SIZE: 4-3/4" x 2-1/4" DIE: N/A APPROVAL DATE: Pfizer Confidential	INSTRUCTIONS: PRINTING TEXT AREA : indicated in grey on schematic above VARNISH AREA Over all Laser Box 50% varnish DO NOT CHANGE LOCATION of Specification number and LOT & EXP SPECIFICATION NUMBER: • 0.062" (3 pts) required space between pic number and laser box • 0.062" (3 pts) minimum space between bar code human readable and Specification number • Specification number font size must be 6 pts. Helvetica Medium Condensed TEXT AREA DIE LINE 50% VARNISH

Uncontrolled document when exported or printed

Pfizer PACKAGE DESIGN & DEVELOPMENT PHARMACEUTICAL PROMOTED PRODUCTS	COMPONENT: Pressure Sensitive Laser Coded Label DESCRIPTION: 180cc - S&T (Barcode Position-option 2) SIZE: 4-3/4" x 2-1/4" DIE: N/A DWG - 101080 - 00 APPROVAL DATE: 08/ Pfizer Confidential	INSTRUCTIONS: PRINTING TEXT AREA : indicated in grey on schematic above VARNISH AREA Over all Laser Box 50% varnish DO NOT CHANGE LOCATION of Specification number and LOT & EXP SPECIFICATION NUMBER: • 0.062" (3 pts) required space between pic number and laser box • 0.062" (3 pts) minimum space between bar code human readable and Specification number • Specification number font size must be 6 pts. Helvetica Medium Condensed TEXT AREA DIE LINE 50% VARNISH

Uncontrolled document when exported or printed