

Sub 77(c) – Yolande Lucire

Why does the TGA not follow these which I receive weekly from the data rich FDA?

----- Forwarded Message

From: FDA MedWatch <fda@service.govdelivery.com>

Date: Tue, 15 Mar 2011 17:42:25 -0500 (CDT)

To: Yolande Lucire and Associates XXXXXXXXXXXXX>

Subject: February 2011 Safety Labeling Changes: 53 Medical Product Labels with changes to Prescribing Information

The MedWatch February 2011 Safety Labeling Changes posting includes 53 products with safety labeling changes to the following sections: BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, PATIENT PACKAGE INSERT, and MEDICATION GUIDE.

The "Summary Page" provides a listing of drug names and safety labeling sections revised:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm242998.htm>

Clicking on a drug product name in the Summary View will take you to the "detailed view" page, which identifies safety labeling sections and subsections revised, along with a brief summary of new or modified safety information.

The following drugs had modifications to the BOXED WARNINGS, CONTRAINDICATIONS and WARNINGS sections:

Avandia (rosiglitazone maleate) Avandamet (rosiglitazone maleate/metformin hydrochloride) and Avandaryl (rosiglitazone maleate/glimepiride) Tablets
Avelox (moxifloxacin hydrochloride) tablets and Avelox (moxifloxacin hydrochloride in NaCl injection) I.V.
Cipro (ciprofloxacin hydrochloride) Tablets, Oral Suspension, IV and Cipro XR (ciprofloxacin extended-release tablets)
Factive (gemifloxacin mesylate) Tablets

Floxin (ofloxacin) Tablets
Heparin Sodium Injection, USP
Humatrope (somatropin [rDNA origin]) for injection
Increlex (mecasermin [rDNA origin] injection
Kaletra (lopinavir/ritonavir) Tablets and Oral Solution
Levaquin (levofloxacin) Tablets, Oral Solution and Injection
Multaq (dronedarone hydrochloride) Tablets
Noroxin (norfloxacin) Tablets
Prilosec OTC (omeprazole magnesium) delayed-release tablets
Promacta (eltrombopag) Tablets
Proquin XR (ciprofloxacin) Extended-Release Tablets
Remicade (Infliximab)
Tekturna (aliskiren) and Tekturna HCT (aliskiren/hydrochlorothiazide) Tablets
Toviaz (fesoterodine fumarate) Extended Release Tablets
Valturna (aliskiren/valsartan) Tablets
Zebeta (bisoprolol fumarate) Tablets

Tell us how we are doing:

[http://survey.foreseeresults.com/survey/display?cid=d509U9xg0gZVxkMRcoMsQg==&sid=link&cpp\[date\]=03_15_2011_1830&cpp\[type\]=l](http://survey.foreseeresults.com/survey/display?cid=d509U9xg0gZVxkMRcoMsQg==&sid=link&cpp[date]=03_15_2011_1830&cpp[type]=l)

You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at www.fda.gov/medwatch/report.htm <<http://www.fda.gov/medwatch/report.htm>>

Follow MedWatch on Twitter <<http://twitter.com/FDAMedWatch>>

Update your subscriptions, modify your e-mail address, or stop subscriptions at any time on your Subscriber Preferences Page <<https://service.govdelivery.com/service/user.html?code=USFDA>> . You will need to use your e-mail address to log in. If you have questions or problems with the subscription service, please contact support@govdelivery.com.

This service is provided to you at no charge by U.S. Food & Drug Administration (FDA) <<http://www.fda.gov/>> .

<<http://www.fda.gov/>> <<http://www.hhs.gov/>>

U.S. Food & Drug Administration (FDA) · 10903 New Hampshire Ave · Silver Spring, MD 20993 · 800-439-1420

----- End of Forwarded Message