



THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FDA Warns Consumers about Counterfeit Drugs from Multiple Internet Sellers

The Food and Drug Administration (FDA) is cautioning U.S. consumers about dangers associated with buying prescription drugs over the Internet. This alert is being issued based on information the agency received showing that 24 apparently related Web sites may be involved in the distribution of counterfeit prescription drugs.

On three occasions during recent months, FDA received information that counterfeit versions of Xenical 120 mg capsules, a drug manufactured by Hoffmann-La Roche Inc. (Roche), were obtained by three consumers from two different Web sites. Xenical is an FDA-approved drug used to help obese individuals who meet certain weight and height requirements lose weight and maintain weight loss.

None of the capsules ordered off the Web sites contained orlistat, the active ingredient in authentic Xenical. In fact, laboratory analysis conducted by Roche and submitted to the FDA confirmed that one capsule contained sibutramine, which is the active ingredient in Meridia, an FDA-approved prescription drug manufactured by Abbott Laboratories.

While this product is also used to help people lose weight and maintain that loss, it should not be used in certain patient populations and therefore is not a substitute for other weight loss products. In addition the drug interactions profile is different between Xenical and sibutramine, as is the dosing frequency; sibutramine is administered once daily while Xenical is dosed three times a day.

Other samples of drug product obtained from two of the Internet orders were composed of only talc and starch. According to Roche, these two samples displayed a valid Roche lot number of B2306 and were labeled with an expiration date of April 2007. The correct expiration date for this lot number is actually March 2005. Pictures of the counterfeit Xenical capsules provided by Roche can be viewed at <http://www.fda.gov/bbs/topics/news/photos/xenical.html>.

Roche identified the two Web sites involved in this incident as brandpills.com and pillspharm.com. Further investigation by FDA disclosed that these Web sites are two of

24 Web sites that appear on the pharmacycall365.com home page under the "Our Websites" heading. Four of these Web sites previously have been identified by FDA's Office of Criminal Investigations as being associated with the distribution of counterfeit Tamiflu and counterfeit Cialis.

At this point, it appears that these Web sites are operated from outside of the United States. Consumers should be wary, if there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required. As a result, FDA strongly cautions consumers about purchasing drugs from any of these Web sites which may be involved in the distribution of counterfeit drugs and reiterates previous public warnings about buying prescription drugs online. Consumers are urged to review the FDA Web page at www.fda.gov/buyonline/ for additional information prior to making purchases of prescription drugs over the Internet.

The 24 Web sites appear on pharmacycall365.com.

AllPills.net
Pharmacy-4U.net
DirectMedsMall.com
Brandpills.com
Emediline.com
RX-ed.com
RXePharm.com
Pharmacea.org
PillsPharm.com
MensHealthDrugs.net
BigXplus.net
MediClub.md
InterTab.de
Pillenpharm.com
Bigger-X.com
PillsLand.com
EZMEDZ.com
UnitedMedicals.com
Best-Medz.com
USAPillsrx.net
USAMedz.com
BluePills-Rx.com
Genericpharmacy.us
I-Kusuri.jp

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