FDA Warns Consumers about Counterfeit Alli

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Washington, DC (rushPRnews) 01/19/10 — The counterfeit products contain controlled substance sibutramine

The U.S. Food and Drug Administration is today warning consumers about a counterfeit and potentially harmful version of Alli 60 mg capsules (120 count refill kit).

Preliminary laboratory tests conducted by GlaxoSmithKline (GSK)—the maker of the FDA approved over-the-counter weight-loss product— revealed that the counterfeit version did not contain orlistat, the active ingredient in its product. Instead, the counterfeit product contained the controlled substance sibutramine. Sibutramine is a drug that should not be used in certain patient populations or without physician oversight. Sibutramine can also interact in a harmful way with other medications the consumer may be taking.

Consumers began reporting suspected counterfeit Alli to GSK in early December 2009. GSK has determined that the counterfeit product has been sold over the internet. However, there is no evidence at this time that the counterfeit Alli product has been sold through other channels, such as retail stores.

The counterfeit Alli product looks similar to the authentic product, with a few notable differences. The counterfeit Alli has:

Outer cardboard packaging missing a “Lot” code;

Expiration date that includes the month, day, and year (e.g., 06162010); authentic Alli expiration date includes only the month and year (e.g.,: 05/12);

Packaging in a plastic bottle that has a slightly taller and wider cap with

coarser ribbing than the genuine product;

Plain foil inner safety seal under the plastic cap without any printed words; the authentic product seal is printed with “SEALED for YOUR PROTECTION”;

Contains larger capsules with a white powder, instead of small white pellets.

Consumers who believe they have received counterfeit Alli are asked to contact the FDA's Office of Criminal Investigations (OCI) by calling 800-551-3989 or by visiting the OCI Web site (http://www.fda.gov/OCI).

Health care professionals and consumers are encouraged to report adverse events that may be related to the use of these counterfeit products to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by mail at: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

Media Web Address:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm197857.htm

About the author:

FDA is an agency within the Department of Health and Human Services and consists of seven centers and offices

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