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FDA NEWS RELEASE

For Immediate Release: May 29, 2012 Media Inquiries: Shelly Burgess, 301-796-4651, shelly.burgess@fda.hhs.gov Consumer Inquiries: 888-INFO-FDA

FDA warns consumers about counterfeit version of Teva's Adderall

Tablets purchased on the Internet contain wrong active ingredients

The U.S. Food and Drug Administration is warning consumers and health care professionals about a counterfeit version of Teva Pharmaceutical Industries' Adderall 30 milligram tablets that is being purchased on the Internet. Adderall, which is approved to treat attention deficit hyperactivity disorders (ADHD) and narcolepsy, is a prescription drug classified as a controlled substance – a class of drugs for which special controls are required for dispensing by pharmacists.

FDA's preliminary laboratory tests revealed that the counterfeit version of Teva's Adderall 30 mg tablets contained the wrong active ingredients. Adderall contains four active ingredients – dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate. Instead of these active ingredients, the counterfeit product contained tramadol and acetaminophen, which are ingredients in medicines used to treat acute pain.

Currently on the FDA's drug shortage list, Adderall is in short supply due to active pharmaceutical ingredient supply issues. Tev continues to release product as it becomes available. Consumers should be extra cautious when buying their medicines from online sources. Rogue websites and distributors may especially target medicines in short supply for counterfeiting.

The counterfeit Adderall tablets are round, white and do not have any type of markings, such as letters or numbers. Any product that resembles the tablets or the packaging in the photos below and claims to be Teva's Adderall 30 mg tablets should be considered counterfeit. The counterfeit versions of Adderall should be considered as unsafe, ineffective and potentially harmful.

Authentic Adderall 30 mg tablets produced by Teva are round, orange/peach, and scored tablets with "dp" embossed on one side and "30" on the other side of the tablet. Teva's Adderall 30 mg tablets are packaged only in a 100-count bottle with the National Drug Code (NDC) 0555-0768-02 listed.

Pictures of the counterfeit version of Teva's Adderall 30 mg tablets and packaging



Press Announcements > FDA warns consumers about counterfeit version of Teva's Adderall

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The Adderall 30 mg product may be counterfeit if:

- 1. The product comes in a blister package.
- 2. There are misspellings on the package.
 - "NDS" instead of "NDC"
 - "Aspartrte" instead of "Aspartate"
 - "Singel" instead of "Single"
- 3. The tablets are white in color, round in shape, and are smooth.

4. The tablets have no markings on them.

Pictures of authentic Adderall 30 mg tablets (immediate release) by Teva (front and back side of tablet)



Anyone who believes they have the counterfeit version of Teva's Adderall 30 mg tablets should not take or should stop taking the product. Consumers should talk to their health care professional about their condition and options for treatment.

Consumers and health care professionals are encouraged to report adverse events or side effects from the suspect counterfeit Adderall to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online: www.fda.gov/MedWatch/report.htm¹³.
- Download form¹⁴ 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.

Consumers who believe they have received counterfeit Adderall should contact the FDA's Office of Criminal Investigations (OCI) at 800-551-3989 or http://www.fda.gov/OCI¹⁵.

For more information:

Buying Medicines and Medical Products Online¹⁶

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