



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: June 18, 2010
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: "Generic Tamiflu"- FDA News Release

SUGGESTED

ACTION: Information provided in case of consumer inquiry

FDA NEWS RELEASE

For Immediate Release: June 17, 2010
Media Inquiries: Elaine Gansz Bobo, 301-796-7567, elaine.bobo@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Warns About Fraudulent Tamiflu
Fraudulent product is dangerous to patients allergic to penicillin

The U.S. Food and Drug Administration today warned consumers about a potentially harmful product represented as "Generic Tamiflu" sold over the Internet. FDA tests revealed that the fraudulent product does not contain Tamiflu's active ingredient, oseltamivir, but cloxacillin, an ingredient in the same class of antibiotics as penicillin.

The agency reminds patients who are allergic to or may have experienced adverse reactions from penicillin products that they are at risk of experiencing similar reactions from cloxacillin. This includes a sudden, potentially life-threatening reaction called anaphylaxis, with symptoms that include difficulty breathing, chest tightness, swelling of the throat or tongue, hives, dizziness, loss of consciousness, or a rapid or weak pulse. To date, the FDA is not aware of any reports of adverse reactions.

There is no FDA-approved generic drug for the prescription product Tamiflu.

The FDA bought the fraudulent "Generic Tamiflu" without a prescription from a website claiming to be an online drugstore that is no longer operational. The fraudulent version is likely to be found

for sale on other websites, however.

“A rogue Internet website marketing drug products may look like a professional and legitimate website, but may actually be an illegal operation,” said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. “Medicines purchased from websites operating outside the law put consumers at increased risk due to a higher potential that the products will be counterfeit, impure, contaminated, or have too little or too much of the active ingredient.”

The FDA-purchased product arrived in an envelope postmarked from India, containing two foil-backed blister packages each with 15 yellow and tan capsules containing white powder (see photos below). The foil backing is printed, and labeled in part, “Oseltamivir Phosphate 75mg. Capsules **TM-FLU** Capsules” and “Manufactured by: TRYDRUGS Pharmaceuticals PVT. LTD.”



Although the FDA actively monitors the Internet and when appropriate purchases and analyzes drug products, consumers who purchase drugs using an online pharmacy can protect themselves by knowing how to recognize a legitimate Internet pharmacy and how to buy medicines safely online. Legitimate internet pharmacies are licensed by the appropriate U.S. Board of Pharmacy and follow the applicable laws and regulations.

Consumers can also be confident that the National Association of Boards of Pharmacy Verified Internet Pharmacy Sites Seal, also known as VIPPS Seal, gives a seal of approval to pharmacy sites that apply and meet state licensure requirements. Legitimate pharmacies that carry the VIPPS seal are listed at www.vipps.info

The FDA advises anyone possessing or encountering any of these fraudulent Tamiflu drugs not to use them and to contact the FDA's Office of Criminal Investigations by calling 800-551-3989, or by visiting the OCI website (<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 fraudulent products to the FDA's MedWatch Program by phone at 800-FDA-1088, by fax at 800-FDA-0178, or by mail at: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

For more information

Buying Prescription Medicine Online: A Consumer Safety Guide
<http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm>