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News & Events

FDA NEWS RELEASE

For Immediate Release: Oct. 15, 2009

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FDA Warns of Unapproved and Illegal H1N1 Drug Products Purchased Over the Internet

The U.S. Food and Drug Administration today warned consumers to use extreme care when purchasing any products over the Internet that claim to diagnose, prevent, treat or cure the H1N1 influenza virus. The warning comes after the FDA recently purchased and analyzed several products represented online as Tamiflu (oseltamivir), which may pose risks to patients.

One of the orders, which arrived in an unmarked envelope with a postmark from India, consisted of unlabeled, white tablets taped between two pieces of paper. When analyzed by the FDA, the tablets were found to contain talc and acetaminophen, but none of the active ingredient oseltamivir. The Web site disappeared shortly after the FDA placed the order. At the same time, the FDA also purchased four other products purported to diagnose, prevent, treat or cure the H1N1 influenza virus from other Web sites.

These products contained various levels of oseltamivir but were not approved for use in the United States. Several of the products purchased did not require a prescription from a health care professional. Additionally, the products did not arrive in a timely enough fashion to treat someone infected with the H1N1 influenza virus, or with an immediate exposure to the virus.

"Products that are offered for sale online with claims to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 influenza virus must be carefully evaluated," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "Medicines purchased from Web sites 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."

Consumers may not know exactly what they are getting when buying such antiviral products on the Internet from an unfamiliar company. Patients who buy prescription drugs from Web sites operating outside the law are at increased risk of suffering life-threatening adverse events, such as side effects from inappropriately using prescription medications, dangerous drug interactions, contaminated drugs, and impure or unknown ingredients found in unapproved drugs. This may particularly be the case in the event of a public health emergency, such as an influenza outbreak, where approved treatment options would be in high demand and expensive, and where drug shortages could occur.

Drugs that are in high demand are vulnerable to counterfeiting and diversion because buyers may be desperate to stock the product, and criminals capitalize on the situation.

The FDA urges consumers to only purchase FDA-approved products from licensed pharmacies located in the United States. Consumers should contact their health care provider if they have any questions or concerns about medical products or personal protective equipment.

The two antiviral drugs approved by the FDA for treatment and prophylaxis of the 2009 H1N1 influenza virus are Tamiflu (oseltamivir phosphate) and Relenza (zanamivir).

Tamiflu and Relenza, in addition to their approved label, have Emergency Use Authorizations that describe specific authorized uses during this public health emergency.

The FDA actively monitors the Internet, and where appropriate, will purchase and analyze drug products.

Consumers can also visit FDA's Web site for [tips about how to protect themselves when buying medicines online](#)¹³.

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Additional Information

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