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## **Photos of unapproved drug products found during the FDA-CBP import blitz**

### **FDA News**

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### **Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments**

The Food and Drug Administration (FDA) and the United States Customs and Border Protection (CBP) agency today announced that their second series of import blitz examinations found 1,728 unapproved drugs, including so-called "foreign versions" of FDA-approved drugs, recalled drugs, drugs requiring special storage conditions, drugs requiring close physician monitoring and drugs containing addictive controlled substances.

These findings provide additional evidence of the serious risks posed by the illegal importation of prescription drugs. Unapproved drugs lack assurances of safety, effectiveness, quality and purity. Moreover, FDA cannot assure the safety and efficacy of a drug product the agency has not reviewed and approved and when FDA has not monitored the manufacturing and quality control processes of the facility in which the product was produced.

The blitz examinations were performed in November 2003 at the Buffalo, Dallas, Chicago and Seattle mail facilities and the Memphis and Cincinnati courier hubs. FDA has been examining trends in the illegal importation of unsafe drugs since 2001 when it undertook a blitz examination at the Carson, Calif. mail facility. In September 2003, FDA released the results of a similar study to the one contained in today's announcement, and which had also been conducted in collaboration with CBP at the Miami, New York (JFK), San Francisco and Carson mail facilities in July and August, 2003. The most recent blitz marked the first time that imported drugs entering the U.S. through courier hubs were targeted in addition to those that pass through mail facilities. Each of these studies has shown that the types of products that are imported into the U.S., as well as the countries from which they originate, vary depending upon the port and facility through which they enter. All of these studies have prompted the same safety concerns about the risks presented by imported drugs. Moreover, the information that FDA has garnered will assist us in doing a better job of quantifying the information obtained as a result of these studies, as well as the risks associated with imported drugs from foreign sources.

FDA and CBP inspectors examined a total of 1,982 parcels that appeared to contain drug products. The majority of the products found in the examined parcels were drugs. The parcels also contained other types of FDA-regulated products, such as dietary supplements and foods, as well as products not regulated by FDA such as pens and notepads.

Parcels were examined irrespective of the country from which they were being exported. Canadian parcels appeared more frequently than parcels from any other country. Of the 1,006 parcels that entered through the mail facilities, FDA determined that approximately

80% of the parcels were exported from Canada, approximately 16% from Mexico, and the remaining 4% were exported from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Commenting on the findings of the recent blitz operations, FDA Commissioner Mark B. McClellan, M.D., Ph.D. said, "We're once again alerting consumers of the risks associated with buying medications from foreign sources outside of the safe, regulated systems of the United States and other nations. Americans deserve access to drugs that are safe, effective and affordable. Compromising safety for price is not in the best interest of the American public."

"During the import blitz, we have examples where our examinations revealed that products were manufactured in countries other than Canada, yet were exported from Canada. For example, at the Dallas, Seattle and Buffalo mail facilities, imported drugs were encountered which were manufactured in Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and a host of other countries. However, in some cases, the drugs that had obviously been manufactured in other countries were exported from Canada," added Commissioner McClellan.

The following examples are typical of the 1,728 unapproved drug products found during the blitzes and illustrate the potential risks they posed to their buyers:

**Improperly Labeled Drugs:** Many of the drugs did not bear adequate labeling or instructions for proper, safe use. For example, some products contained strictly foreign labeling, many contained dual labeling (in both English and a foreign language) and several contained no labeling whatsoever and were simply loose in plastic baggies or wrapped in tissue paper. Moreover, many of the imported drugs, including those from Canada, were shipped in containers which appeared to be intended for pharmacists without U.S. approved patient labels. This common problem is especially concerning in light of the special risks associated with many of the drugs noted below.

**Controlled substances:** Ratio-Lenoltec with codeine, codeine, diazepam (Valium), lorazepam (Ativan), Tylenol 3 (containing codeine), and clonazepam are controlled substances that have abuse potential and can be dangerous when consumers take them inappropriately and without a physician's supervision.

**Potentially recalled drugs:** Serevent Diskus and Flovent Diskus medicines are used in the U.S. and Canada to treat asthma and chronic obstructive pulmonary disease (COPD). Flovent Diskus is approved in the U.S., but is not currently marketed in the U.S. The blitz results indicate that American consumers were sent these drugs from Canada. Shortly after the blitz operations, certain lots of the Canadian versions of these drugs were recalled in Canada. In the U.S., the import of these lots was the subject of an FDA consumer alert because of concerns that the product's delivery system might not function properly and might deliver too little of the drug - or none at all. Thus, at the time of importation, American consumers had no way of knowing if the Canadian products they were purchasing would subsequently be recalled. However, the FDA-approved product, sold in the U.S. through legitimate marketing channels, did not have the delivery system problem and was not subject to the recall. A picture of one of the Serevent Diskus products found during the blitz is available online at <http://www.fda.gov/bbs/topics/NEWS/photos/serevent.html>

**So-called "foreign versions" of FDA approved drugs:** The FDA approved versions of many of these products pose safety concerns that require use only under the close supervision of a health care professional. Variations from U.S. standards in potency and purity of unapproved versions may raise additional concerns regarding both safety and efficacy. Examples of these products include:

- **APO-Tamox** - an unapproved, foreign version of the anti-cancer drug Tamoxifen;
- **APO-Warfarin** - an unapproved, foreign version of the blood thinner warfarin. The potency of warfarin may vary depending on how it is manufactured, and the drug must

be carefully administered and monitored by a health professional in order to prevent serious bleeding problems;

- **APO-Carbamazepine** - an unapproved, foreign version of the anti-convulsant drug carbamazepine which requires initial screening and monthly monitoring of blood and platelet counts to ensure safe use;
- **APO-Allopurinol** - an unapproved, foreign version of a drug used in the management of certain types of cancer. Allopurinol, which requires periodic monitoring of kidney function during the first few months of treatment, and can cause kidney failure with underlying renal disease;
- **Alti-azathioprine** - an unapproved, foreign version of an immunosuppressant drug. This drug can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development. The FDA approved version of this drug requires regularly scheduled monitoring of blood counts, and
- **Human Growth Hormone** - This is a widely used drug indicated for a number of conditions in both children and adults. It can have serious side effects (for example, it can unmask or worsen diabetes and cause elevation of pressure in brain) if used inappropriately or in excessive doses.

**Drugs requiring risk management and/or restricted distribution programs:** For example, Canadian-manufactured isotretinoin, a drug to treat a severe form of acne, was shipped without any assurance that its use would be monitored by a physician. In the U.S., isotretinoin is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks, such as birth defects that may occur following the use of the drug. U.S. prescribers are also expected to attest, prior to prescribing isotretinoin, that pregnancy testing has been done to confirm that the patient is not pregnant.

Drugs that require initial screening or periodic monitoring of patients: Initial screening and periodic patient monitoring by a medical professional (for example, monitoring liver function or blood parameters) are recommended in FDA's approved labeling for the following drugs which were found during the blitz operation:

- **Casodex** is used in the treatment of prostate cancer. A medical professional must rule out baseline liver disease prior to treatment initiation and should monitor liver function tests periodically during treatment.
- **Coumadin** and **Warfarin** are anticoagulants that require initial and periodic monitoring of blood parameters to avoid bleeding problems.
- **Clomid** is used in the treatment of ovulatory dysfunction. A medical professional must rule out liver, thyroid, and adrenal dysfunction before beginning treatment and should also perform monitoring during treatment to avoid ovarian hyperstimulation.
- **Metformin** is an oral hypoglycemic that requires regular monitoring of blood parameters and pre-treatment and ongoing assessments of kidney function to reduce the risk of development of lactic acidosis.
- **Tamoxifen** is a drug for which a medical professional must rule out uterine malignancy prior to, and regularly during, treatment.
- **Amitriptyline** (Elavil) is an anti-depressant for which cardiovascular disorders must be ruled out prior to treatment.
- **Lithium carbonate** is an anti-psychotic also used to treat manic depression. Individualized dosing and careful monitoring of serum levels is required for this drug to avoid life-threatening toxicity.

**Drugs requiring careful dosing:** For example, Synthroid (levothyroxine), Glucophage (metformin), Dilantin (phenytoin), digoxin, theophylline, Coumadin (warfarin) all require individualized titration of the dose prescribed and very careful dosing in order to avoid serious and potentially life-threatening side effects.

**Drugs with clinically significant drug-drug interactions:** Zocor (simvastatin), imipramine, Viagra (sildenafil citrate) and tramadol can be associated with clinically

significant interactions with other drugs the buyer may be taking.

**Biologic drugs which should be administered by a healthcare provider and are not licensed by FDA** - For example, Influenza Virus Vaccine approved in Canada but not licensed by the FDA was encountered.

**Investigational Products:** These products should only be shipped pursuant to FDA's IND regulations, which assure that patients who use investigational products are fully informed and are not exposed to unreasonable risks. When these products are shipped through the mail, and used outside of the protections established to protect patients involved in clinical trials of experimental drugs, there is a significant risk that a patient may be harmed. Examples of investigational products found during the blitz examinations include the drug atrasentan labeled as "medical study cancer samples."

In general, FDA and CBP do not have sufficient resources to perform comprehensive examinations of the huge number of parcels brought to the U.S. by mail and commercial couriers. Instead, the FDA intends to continue to cooperate with CBP in conducting more "blitz" exams of individual drug imports. To this end, the FDA will endeavor to:

- use its limited investigatory and regulatory resources more strategically to focus on the foreign sources of illegal, unsafe imported drugs;
- work with commercial shippers and credit institutions to identify shipping patterns of known vendors of unsafe drugs so that it can more accurately target their shipments and sources;
- form partnerships with other federal, state, and international regulatory and law enforcement agencies to combat these illegal imports; and
- educate the public about the dangers of illegally imported drugs.

Additional information about the risks of buying illegally imported drugs is available at <http://www.fda.gov/oc/opacom/hottopics/importdrugs/default.htm>.

Details regarding the first joint FDA/CBP import blitz, which occurred in July-August 2003, are available online at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html>.

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#### **Imported Drugs with Inappropriate Labeling**

- Diamond-shaped Blue Tablets
- Miscellaneous Drugs
- Tablets of Various Shapes and Colors

#### **Imported Drugs with Foreign Labeling**

- Ansomone Growth Hormone (1 of 5)
- Ansomone Growth Hormone (2 of 5)
- Ansomone Growth Hormone (3 of 5)
- Ansomone Growth Hormone (4 of 5)
- Ansomone Growth Hormone (5 of 5)
- Botox
- Fluviral
- Human Growth Hormone (1 of 2)
- Human Growth Hormone (2 of 2)
- Pegetron

- [Injectable Drugs](#)
- [Zocor](#)
- [19 drugs in one parcel](#)

**Imported Drugs with Various Safety Concerns**

- [Celebrex](#)
- [Flomax](#)
- [Lipitor](#)
- [Miracle II \(1 of 2\)](#)
- [Miracle II \(2 of 2\)](#)
- [Serevent Diskus](#)

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