



U.S. Food and Drug Administration



FDA News

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Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-
FDA

FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments

A recent series of spot examinations of mail shipments of foreign drugs to U.S. consumers conducted by the Food and Drug Administration (FDA) and U.S. Customs and Border Protection (CBP or Customs) revealed that these shipments often contain dangerous unapproved or counterfeit drugs that pose potentially serious safety problems. This joint operation was carried out to help FDA and CBP target, identify, and stop counterfeit and potentially unsafe drugs from entering the United States from foreign countries via mail and common carriers. It was also designed to help FDA and CBP assess the extent of this problem.

These "blitz" exams were conducted in the Miami and New York (JFK) mail facilities from July 29-31, 2003, and the San Francisco, and Carson, Calif., mail facilities from August 5-7 2003, to obtain a representative picture of products entering the United States. In each location, packages shipped by international mail through U.S. Postal Service facilities over a 3-day time span were examined. For the purposes of these blitzes FDA and CBP identified, through review of historical data and experience, those packages likely to contain drug products. For example, packages were considered if they were from countries from which drugs are known to be exported via the mail. Due to the speed at which parcels are automatically processed and transported through the mail facilities, country of origin was the only specific criterion that could be consistently applied to all parcels.

Approximately 100 parcels (each of which may have contained multiple drug products) per day per facility were selected based upon their country of origin and historical experience. They were subsequently opened by CBP and jointly examined by both Agencies. Those in violation of CBP provisions were held by CBP. Those in violation of FDA regulations were detained by FDA.

In general, FDA and CBP do not have sufficient resources to perform comprehensive examinations of all mailed packages due to the huge volume of parcels entering the United States through international mail and courier services, the consuming time requirements for processing and returning illegally imported drugs, and multiple, competing enforcement priorities. For example, the Carson, Calif., mail facility alone receives over 10,000 parcels per day.

Although many drugs obtained from foreign sources purport, and may even appear to be, the same as FDA-approved medications, these examinations showed that many are of unknown quality or origin. Of the 1,153 imported drug products examined, the overwhelming majority, 1,019 (88%), were violative because they contained unapproved drugs. Many of these imported drugs could pose clear safety problems.

These drugs arrived from many countries. For example, 15.8% (161) entered the U.S. from Canada; 14.3% (146) from India; 13.8% (141) from Thailand; and 8.0% (82) from the Philippines. The remaining entries came from other countries.

“This joint effort with CBP illustrates the real and serious public health risks created by the importation of unapproved drugs,” said Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs. “To protect Americans from unsafe imported drugs, we are working to target our enforcement resources as effectively as possible against those products that pose a threat to the health of consumers and the safety and security of our drug supply.”

“This action represents an important step forward in keeping harmful or illegal drugs from entering the country,” said Customs and Border Protection Commissioner, Robert C. Bonner. “Although CBP’s priority mission is preventing terrorists and terrorist weapons from entering the United States, CBP continues to perform its traditional mission by working with the FDA to identify and interdict illegal and dangerous drugs that could threaten public health and safety.”

The potentially hazardous products found in these blitz exams revealed:

- **Drugs different from those approved by FDA** -- Drugs that FDA has never approved are being imported. For example, Roaccutane (an unapproved version of Accutane) is being imported from Thailand. In the United States, prescribers of Accutane (a drug to treat a severe form of acne) are required to monitor patients to avoid certain serious risks such as birth defects that may occur following use of the drug. Taro-warfarin (an apparently unapproved version of Warfarin) from Canada is also being imported. Warfarin is used to prevent blood clotting and its potency may vary depending on how it is manufactured. Because it can cause serious, life-threatening bleeding if not administered appropriately, it requires careful monitoring by a health care provider of a patient’s blood count during treatment.

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- **Drugs requiring careful dosing** -- Drugs such as unapproved versions of Dilantin (from Philippines); unapproved versions of Synthroid (from Canada); and unapproved versions of Glucophage (from Canada and Philippines) that require individual titration and very careful dosing to avoid serious life-threatening side effects are being imported.

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- **Drugs with inadequate labeling** -- Moreover, most of these drugs came without adequate labeling or instructions for proper, safe use. Some of the drug labeling was not in English and important information about matters such as proper dosage was often missing.

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- **Drugs inappropriately packaged** -- In some cases, these drugs were inappropriately packaged in baggies, tissue paper, or letter envelopes. In other instances, the imported drugs arrived crushed and broken.

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- **Drugs withdrawn from the market** -- Consumers are importing drugs that FDA has withdrawn from the market for safety reasons. For example, one unapproved drug that came from Mexico, Buscapina, appears to be the drug Dipyrone that was removed from the U.S. market in 1977 because of several reports of the development of severe blood disorders following the drug’s administration, some of which resulted in fatalities;

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- **Animal drugs not approved for human use** -- Animal drugs that FDA has not approved for humans use are being imported. For example, Clenbuterol, a drug approved for the treatment of airway disease in horses but that has not been approved for human use and has been banned by the International Olympic Committee as a performance enhancing drug, came from Costa Rica and China;

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Drugs with dangerous interactions -- Drugs such as ketoconazole (from Thailand) – unapproved versions of Viagra (from United Kingdom, India, Philippines and Japan); and unapproved versions of Zocor (from Canada) are being illegally imported and have the potential to cause clinically significant interactions with other drugs which consumers may be taking;

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Drugs that carry risks requiring initial screening and/or periodic patient monitoring -- Drugs such as unapproved versions of Lipitor (from Ireland, Thailand, Japan, Philippines, Canada, Argentina, New Zealand, England and Brazil); and unapproved versions of Pravachol (from Canada) are being illegally imported. Initial screening and periodic patient monitoring by a medical professional (e.g. monitoring liver function) are recommended in FDA's approved labeling for these drugs to help assure their safe use;

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Controlled substances-- Over 25 different controlled substances were offered for import including Diazepam (from Canada, Thailand, Philippines, Costa Rica, Malaysia, New Zealand, and India); Xanax (from Philippines); Codeine (from Canada, Philippines, Costa Rica, United Kingdom, New Zealand, Thailand, Guatemala, China, Peru, and Taiwan); Valium (from Philippines and Thailand); and anabolic steroids (from Costa Rica). These drugs were referred to the Drug Enforcement Administration. Controlled substances pose serious safety issues for consumers because they are dangerous narcotics that have abuse potential for patients who take them inappropriately or without the proper physician supervision.

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The blitz is also helpful in understanding trends in the illegal importation of unsafe drugs. In 2001, FDA conducted a similar analysis that prompted the same concerns about the risk of these imported drugs. Compared to the 2001 results at the Carson mail facility, this most recent blitz uncovered a somewhat larger number of imports, including a larger number of unapproved drugs and drugs that appeared to be counterfeits. The blitz FDA conducted at the Carson mail facility in 2001, as well as the most recent blitz conducted by FDA in coordination with Customs, illustrate the type of regular surveillance activities involving imported drug products that FDA undertakes. As a result of the current blitz, we are re-evaluating the enforcement strategies and objectives we use to target the entry of unapproved and/or counterfeit drug products through international mail facilities.

"There is no evidence that unapproved imported drugs are becoming any safer or more reliable," said Dr. McClellan. "Given FDA's limited resources and authorities to detect and block potentially unsafe imports, we are concerned about any measures that would increase the flow of these unapproved drugs, or provide easier channels for them to enter the United States."

The blitz results will assist the Agency in its efforts to:

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utilize its investigatory and regulatory resources more strategically to focus on the foreign sources of illegal, unsafe imported drugs;

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identify shipping patterns specific to identified sources of unsafe drugs so that it can target future shipments and sources of such drugs; and

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seek out partnerships with other federal and state agencies to combat this problem.

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In addition, FDA will continue its efforts to educate the public about the dangers of drugs through illegal, poorly-regulated, and potentially unsafe foreign channels.

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