



U.S. Food and Drug Administration
Protecting and Promoting Public Health

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Cargo Theft: FDA Perspective

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Cargo Theft





Overview

- FDA experiences
- Challenges
- FDA actions
- Corporate responsibility
- Next steps

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Cargo Thefts

Resources for You

- Report Suspected Criminal Activity
- For Health Professionals
- For Consumers
- For Industry



FDA is committed to protecting consumers from the threat of stolen, counterfeit, and diverted FDA-regulated products such as prescription or over-the-counter medicines, medical devices, or infant formula. FDA created this webpage to provide timely notice to the public about cargo thefts involving FDA-regulated products that have been stolen either from warehouses or tractor-trailers. These stolen products may put American consumers at risk because they may not have been stored or handled properly or may have been tampered with while out of the normal supply chain, and therefore may cause harm. Stolen products may enter the supply chain as a result of illegal transactions by individuals and distributors.

By following the advice contained in the posted notices, consumers, retailers, healthcare professionals, pharmacies, and wholesalers/distributors can help protect themselves and others from purchasing, receiving or using stolen products.

e-News Archives

NABP e-News: April 30, 2009

Educational, Regulatory and Association News for the State Boards of Pharmacy

NABP helps....**NABP Asks Boards' Help in Tracing Pharmaceutical Cargo Theft of Copaxone**

The FDA OCI has notified NABP of a recent theft of the pharmaceutical Copaxone[®]. Approximately 14 pallets/994 cartons/5,962 packs of Copaxone (glatiramer acetate) 20 mg, a non-controlled substance with Batch/Lot #P53159 and an expiration date of January 2011, were stolen during the week of April 13-17, 2009. The tractor-trailer was recovered at a rest stop on the New Jersey Turnpike on April 20. Unfortunately, its contents were emptied. Corporate security from TEVA indicated that the remainder of the specific Batch/Lot #P53159 was recalled so that if that particular product with Batch/Lot #P53159 is being distributed, offered for sale, or dispensed, it would be the stolen product.

Copaxone is a unique product and is used only to treat patients suffering from multiple sclerosis. If the product is not stored below 74 degrees and out of the sunlight, it becomes ineffective and the product may not be safe for use.

NABP requests that the boards of pharmacy provide this information to the pharmacists in their states and ask them to immediately notify the FDA OCI if they are contacted by individuals offering to sell this product or if they have purchased this product or know of anyone who may be involved with this theft and the distribution of this product.

Any information should be provided to Special Agent Gregg Goneconto or Special Agent Nancy Kennedy at OCI headquarters (800/551-3989), or via the OCI Web page at <http://www.fda.gov/oci/contact.html>.



Market withdrawals... significant impact

URGENT MARKET WITHDRAWAL FOR SPECIFIC LOTS

June 25, 2009

Dear Health Care Professional:

On June 17, 2009, a transport trailer containing Astellas prescription drug products in transit from our distribution center was stolen. These products have not been recovered, and Astellas cannot verify that the products contained in the stolen shipment have been properly handled and stored. Therefore we are voluntarily withdrawing from the marketplace all quantities of the lots affected in order to best assure that these stolen drug products do not illegally re-enter the supply chain. Our paramount concern is the safety of patients and this voluntary withdrawal is to assure the safety and quality of our products in the marketplace.

Attached is a listing of the withdrawn lots for each of the products affected by this theft.

Medwatch Reports linked to stolen product



U.S. Department of Health & Human Services

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Update to FDA Alert About Stolen Insulin

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The Food and Drug Administration (FDA) is reminding the public that stolen vials of the long-acting insulin Levemir made by Novo Nordisk Inc. still may be on the market. FDA first alerted the public to the theft in June 2009.

Evidence gathered to date suggests that the stolen insulin was not stored and handled properly and may be dangerous for people to use. The agency has received multiple reports of patients who suffered an adverse event due to poor control of glucose levels after using a vial from one of the stolen lots.

In June 2009, FDA reported that three lots of Levemir totaling 129,000 vials had been stolen in North Carolina. So far only about 2 percent of the total amount stolen has been recovered.

The agency continues to aggressively investigate this matter and is asking for the public's help in reporting any information regarding these vials to FDA's Office of Criminal Investigations (OCI) by calling 800-551-3989 or by visiting the [OCI Web site](#).

Advice for Patients

- Check your personal supply of insulin to determine if you have Levemir insulin from one of the following lots: XZF0036; XZF0037; XZF0038. You can locate the lot number on the side of the box of insulin and also on the side of the vial.
- Do not use your Levemir insulin if it is from one of these lots. Replace it with a vial of Levemir insulin from another lot. If you must switch to another brand of insulin for any reason, first contact your health care provider because another insulin product may require adjustments in dosing.
- Always look at your insulin carefully before using it. Levemir is a clear and colorless solution.



**Medical devices
too....**

PRESS RELEASES

VISTAKON® IN THE NEWS

INFORMATION NOTICE ON STOLEN ACUVUE® OASYS™ BRAND CONTACT LENSES FROM JOHNSON & JOHNSON VISION CARE, INC.

JACKSONVILLE, Fla (February 03, 2010) – Johnson & Johnson Vision Care, Inc. is working with the U.S. Food and Drug Administration's Office of Criminal Investigations, the Orlando, FL District Office, and other law enforcement officials to recover cases of certain lots of retail-ready contact lenses which were stolen from a secure freight consolidation facility in Elizabeth, NJ sometime between January 16-17, 2010. The products stolen were full cases of ACUVUE® OASYS™ Brand Contact Lenses in a wide variety of corrective prescriptions and lots. In each case the stolen product represents a small portion of the product lots.

The FDA is requesting that information regarding individuals that may have been involved with this theft and information about any suspected stolen contact lens products be reported to FDA's Office of Criminal Investigations (OCI) by calling 800-551-3989 or by visiting the OCI Web Site (<http://www.fda.gov/OCI>).

All Johnson & Johnson Vision Care, Inc. contact lens products are delivered in sealed cartons and have tamper-evident foil seals on the blister pack holding each lens. Johnson & Johnson Vision Care, Inc. and the FDA advise eye care practitioners, retailers, and consumers to check all contact lens products for signs of tampering or damage prior to purchase and/or use. Do not use the product if it has been removed from the sealed carton or if the foil seal appears to have been disturbed in any way. Contact lenses are medical devices that require a prescription for purchase. It is always advisable to purchase product only from trusted and reliable sources that verify

Challenge...many different types of products in one theft

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Update to Notification of Stolen Johnson & Johnson Family of Consumer Companies Products

FDA posts press releases and other notices from firms as a service to consumers, the media, and other interested parties

The Johnson & Johnson Family of Consumer Companies is working with *the U.S. Food and Drug Administration, Office of Criminal Investigations (FDA)*, and other law enforcement officials to recover cases of select lots of retail non-prescription consumer healthcare and nutritional products. The products were stolen in Pennsylvania from a shipping truck en route from Tobyhanna, PA to a retailer in Michigan, between April 17th and 18th, and include small quantities of consumer health and nutritional products from the following brands: AMBI, AVEENO, BAND-AID, BENADRYL, BENGAY, CALADRYL, CAREFREE, DESITIN, CLEAN&CLEAR, COACH, CORNHUSKERS, CORTAID, DRAMAMINE, EPT, IMODIUM, J&J FIRST AID, JOHNSON'S, KY, LACTAID, LISTERINE, LUBRIDERM, MONISTAT, INFANTS' MOTRIN IB, CHILDREN'S MOTRIN IB, MOTRIN IB, MYLANTA, INFANTS' MYLICON, NEOSPORIN, NEUTROGENA, NIZORAL, OB, PEPCID, PURPOSE, REACH, REMBRANDT, ROC, ROGAINE, ROLAIDS, SHOWER TO SHOWER, SIMPLY SLEEP, SPLENDA, ST. JOSEPH'S ASPIRIN, STAYFREE, SUDAFED PE, SUN CRYSTALS, TUCKS, INFANTS' TYLENOL, CHILDREN'S TYLENOL, TYLENOL, VIACTIV, VISINE, ZYRTEC.

The Johnson & Johnson Family of Consumer Companies, along with FDA and local authorities, has initiated efforts to locate the stolen product and identify the individuals who were involved in the theft.

The Johnson & Johnson Family of Consumer Companies and the FDA are asking for the public's help in reporting any information regarding the stolen consumer healthcare products to FDA's Office



Cargo theft: FDA activities

- Established internal rapid response SOP
- Created Cargo theft webpage
- Active FDA/OCI engagement with law enforcement and manufacturers re: stolen products
- Public alerts
- Supply chain stakeholder alerts
- Stakeholder meetings re: what's needed to stop this public health threat
- Stakeholder letter

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FDA Cargo/Warehouse Letter to Stakeholders



Department of Health and Human Services

FDA Cargo/Warehouse Letter to Shareholders

April 28, 2010

Food and Drug Administration
Rockville, MD 20857

Dear Stakeholder:

FDA is very concerned about the increase in cargo and warehouse thefts of FDA regulated products, including prescription and over-the-counter medicines, vaccines, medical devices, and infant formula. These crimes threaten the public health because product that has left the legitimate supply chain poses potential safety risks to consumers. There have been several cases where patients experienced adverse reactions from stolen drugs, reactions that were most likely due to improper storage and handling. We do not want to see this increase in thefts continue. We would like to share our thoughts on steps that your members should take to minimize the risk of such thefts, as well as how FDA can work together with your members when a theft has occurred to address the public health risks associated with the stolen products.

Of course, the best intervention is to prevent these thefts from occurring in the first place. Firms engaged in providing medical products and infant formula to the public have a fundamental responsibility to continuously review their warehouse physical security and security practices and procedures for transporting products to ensure that



Stakeholder letter – April 2010

- Supply chain stakeholders should ensure that measures are in place to minimize the risk of warehouse and cargo theft
- Supply chain stakeholders should continuously review
 - Physical security of warehouse
 - Current security practices
 - Procedures for transporting products
- Supply chain partners should ensure that business partners & carriers review and have strengthened storage and in-transit security practices
- Procedures to take when a theft occurs
 - Notify FDA/OCI
 - Working with FDA District Office
 - Action Plan
 - Notification



Potential Q's from FDA regarding cargo/warehouse theft

- Who are the firm's contact(s) authorized to discuss product removal from the market as well as public notification of the cargo theft?
- What has the firm determined about the theft?
- What are the details of all products that were stolen, to include:
- Were entire lots stolen? Had a portion of the stolen lot(s) been legitimately distributed prior to the theft?
- What is the quantity of related lots of product in legitimate distribution and/or secured?
- Have any controls been put into place since the theft to stop distribution of other products from the affected lots - or of similar products?
- Has the firm performed a risk assessment to determine the public health risk posed by the products that were stolen? What factors has the firm determined will affect the risk posed by the products that were stolen, e.g. changes in storage or handling conditions?



Potential Q's from FDA regarding cargo/warehouse theft

- Does the firm intend to inform or warn the public about the products that were stolen? If so, how and when? If the firm intends to issue a Press Release, is the firm willing to share the Press Release with FDA for input prior to issuance? If not, how has the firm handled the situation so as to obviate the need for public notice?
- Has the firm already sent any communication(s) to customers about the stolen products?
- Has/will the firm develop an Action Plan in response to this theft? Will the firm share the Action Plan with FDA? When?
- How can consumers identify a product from the stolen lot(s) What steps should consumers take who receive the stolen product, e.g. discontinue use, consult physician, return product, etc.
- Does the firm have any information regarding where this product will be sold/distributed?
- Has the firm received any consumer complaints or reports of injuries or illnesses associated with product that could have been stolen?



Next Steps

- Corporate responsibility
- Stakeholder meetings
- Best practices?
- Role of Boards of Pharmacy?
- Other.....



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COMMENTS OR QUESTIONS???

THANK YOU!!!!

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