



April 28, 2010

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 measures are in place to minimize the risk of warehouse and cargo theft. These measures are important throughout the supply chain—starting from the point of manufacturing, continuing through the distribution of the product and to the retail outlet or other point where the product will be sold. Your members should ensure that their business partners and carriers review and have strengthened their storage and in-transit security practices as well. Your members need to be one-step ahead of thieves in securing their warehouses and product transport.

When a theft occurs, FDA is committed to work with the affected firm to minimize the public health risks and ensure an appropriate public health response. The agency has developed streamlined procedures to rapidly respond to reports of theft and ensure consistency as we work with firms that have experienced a cargo or warehouse theft.

We would like your members to promptly notify FDA's Office of Criminal Investigations (OCI) as soon as possible when a theft has occurred by contacting OCI's Headquarters office at 800-551-3989 or by accessing the OCI web site (www.fda.gov/oci). OCI will ask for information about the theft to assist FDA in evaluating an appropriate regulatory response. In the attached Appendix A to this letter, we have listed the types of questions that an FDA District Office may ask about the incident. FDA also encourages prompt reporting to law enforcement agencies.

Typically, FDA's District Office closest to a firm's corporate headquarters will follow up with their regulatory contact. The District Office will request that the firm provide

information pertaining to the stolen products, including a risk assessment and an action plan, as expeditiously as possible. (See Appendix A.)

In some cases, the appropriate public health response may be a market withdrawal for product already in the supply chain with the same lot numbers as the stolen product.

We recognize the impact that such a withdrawal may have on consumers, the supply chain, and a firm's business operations, and the agency is ready to work closely with firms to determine the appropriate steps to consider in order to protect the public. Depending on the circumstances, a prompt and effective response to a theft will reduce the need for such a market withdrawal.

Prompt public notification of the theft is a critical step in protecting the public health because it alerts others in the supply chain and the public to look out for the stolen products and to be skeptical of offers for these products at unusually low prices or from a person outside the legitimate distribution chain. In addition, if persons in the supply chain are looking out for these products, it becomes more difficult for the thieves to sell the products back into the legitimate supply chain. If a firm experiences a cargo or warehouse theft, we strongly encourage it to prepare a public notice for posting on its website or as a press release as soon as possible after the theft. FDA is ready to provide comment on the public notice in an expeditious manner if the firm would like to share it with the agency before release. FDA's District Office will coordinate this review with the firm. FDA will typically provide a link to the firm's public notification on FDA's new Cargo Theft website.

<http://www.fda.gov/ICEC/CriminalInvestigations/ucm182888.htm>

As you may know, FDA has been working with manufacturers, wholesalers, and retailers on ways to further secure our nation's supply chain from counterfeit, diverted, unapproved, and otherwise misbranded or adulterated products. We have now added stolen products to this effort. FDA is working with the medical products and infant formula supply chain to identify best practices and provide other guidance on how to prevent and respond to cargo/warehouse thefts.

FDA hopes and expects that your members and others in the supply chain will immediately review their in-transit and warehouse security practices and take proactive measures to prevent opportunities for theft. It is also prudent for your members to plan in advance, for how they would respond to such an incident, since swift action is essential.

We look forward to continued dialogue with participants in the supply chain to identify best practices and other steps that can be taken to further ensure that American consumers can be confident about the safety and quality of medical products and infant formula sold in the U.S.

If you have any questions related to this letter or cargo theft generally, please contact Dr. Ilisa Bernstein, Director of Pharmacy Affairs, FDA, Office of the Commissioner, Office of Policy at 301-796-4723 or ilisa.bernstein@fda.hhs.gov.

Sincerely,


Michael A. Chappell
Acting Assistant Commissioner
for Regulatory Affairs

APPENDIX A – Potential Questions from FDA Regarding Cargo/Warehouse Theft Incident

- 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:
 - Finished product (prescription, OTC, infant formula), samples, bulk product, API etc.;
 - Description of product stolen (capsules, injectables, powders, etc.) ;
 - Quantity of each product stolen;
 - Description of packaging/containers;
 - Lot number(s) and NDC number(s);
 - Storage/handling requirements for the product(s); and
 - Tampering protections in packaging?
- 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?
- 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?