

**FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM
DIRECTIVES**

GENERAL OR MULTIDISCIPLINE

FDA'S RESPONSE TO CARGO THEFTS

Effective Date: 03/23/2012

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide a general procedure for determining FDA's regulatory response when a cargo theft involving an FDA-regulated product has occurred. When followed in conjunction with the established procedures for product removal from the market, public notice, and handling medical product shortages, if applicable, the procedures described in this document will ensure that FDA's regulatory response to cargo thefts is consistent and effective.

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. This procedure outlines the steps that FDA may take in addressing cargo thefts that are reported to the agency to minimize the public health risks associated with the stolen products.

2. SCOPE/POLICY

The SOP addresses FDA's response to cargo thefts of FDA-regulated products as determined by the Centers, ORA, OCI, and the Commissioner's

Office via the Cargo Theft Response Team (CTRT), a workgroup comprised of representatives from those parts of FDA (Appendix A).

- A. Notification to the FDA of a cargo theft may be received by the Centers, any of the various field or headquarters agency offices, or any other part of the agency. If the report is received by a part of the agency other than OCI, the recipient will immediately notify OCI Headquarters so that OCI can verify the theft with the firm and initiate fact finding for the agency. OCI will lead the criminal investigation for the agency and will communicate/coordinate with other federal, state, and local law enforcement agencies.
- B. OE will coordinate the agency's regulatory response to address the potential public health concerns associated with the stolen products re-entering the market. OE will coordinate FDA's contact with the firm through the appropriate District Office. OE will also coordinate the agency's assessment of the risk to public health from the cargo theft (s) by working with the CTRT member for the appropriate Center(s) for a risk assessment. OE will also coordinate the development of the appropriate regulatory response to the firm's action plan regarding the theft through the CTRT. If FDA action is required, the Centers and ORA shall follow established procedures for any such action(s). OE will ensure dissemination of public notifications of cargo theft incidences whether issued by FDA or the firm(s).
- C. If a firm is nonresponsive to FDA's request for information related to the cargo theft or if the firm's action plan is inadequate, or if the firm is unwilling or reluctant to alert the public to the cargo theft, the CTRT will consider the option of providing the public with the relevant facts about the cargo theft and to address the public health risk associated with that theft.

3. REFERENCES

- A. The RPM, Chapter 6, Section 6-5-2, states that "The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters. FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI".
- B. The IOM, Chapter 8, Subchapter 8.9.1 states "The Office of Criminal Investigations (OCI) has the primary responsibility for all criminal investigations conducted by the FDA, including suspected tampering incidents and suspected counterfeit products. Similarly, OCI has primary responsibility and is the primary point of contact for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA regulated products."

4. RESPONSIBILITIES/CONTACTS

- A. OCI Headquarters - OCI Headquarters will make the initial contact with the responsible firm to verify the cargo theft and will immediately thereafter provide any information received from the firm to the CTRT in accordance with paragraph A of section IV. OCI is a member of the Pharmaceutical Cargo Security Coalition. The group is comprised of representatives from local, state and Federal law enforcement as well as the pharmaceutical industry and FDA. The focus of this group is to share intelligence related to pharmaceutical cargo thefts, identify emerging trends and organized criminal groups, and to identify and implement measures designed to better secure pharmaceutical products while in transit from the manufacturing facility to the distribution points. OCI's primary objective related to cargo theft investigations is to identify, target and dismantle illicit prescription drug diversion networks that threaten the legitimate pharmaceutical supply chain. FDA considers cargo thefts to include tractor-trailer and warehouse thefts of FDA-regulated products, such as prescription drugs, OTC drug products, infant formula, or medical devices which may pose a threat to the public health or a risk to the legitimate supply chain. OCI cargo theft investigations may be initiated because the criminal organizations behind such thefts are suspected of being associated with drug diversion networks.
- B. Office of Enforcement - OE will coordinate FDA's initial regulatory response to any potential public health and/or supply chain concerns from the cargo theft.
- C. District Office - The District Office will contact the firm within 24 hours after receiving notice of a cargo theft from OE for the purpose of obtaining the firm's action plan to ensure the overall quality and safety of its product in light of the cargo theft. The District will immediately notify OE of the firm's response to the cargo theft. Thereafter, the District will communicate with the firm as requested by the CTRT.
- D. Center(s) - The Center(s) will participate as a member of the CTRT and provide consultation and expertise as needed regarding the public health risk and the threat to the legitimate supply chain from the cargo theft.
- E. Division of Import Operations and Policy - DIOP will participate as a member of the CTRT, as appropriate, to ensure that adequate screening is in place when information is received indicating that stolen products may be destined for the U.S. market. As warranted by the circumstances, DIOP may coordinate coverage with other government agencies.
- F. Office of Commissioner -

1. Office of Public Affairs - The press office in OPA will work with the CTRT and the appropriate Center(s) on drafting an FDA Consumer Alert as well as obtaining the necessary clearance for a press release from the agency and HHS.
2. Office of International Programs - OIP will work with the CTRT and the appropriate Center(s) to provide notice of a cargo theft to foreign regulators.
3. Office of Emergency Operations - OEO will participate as a member of the CTRT when a report of an injury or illness related to the use of or exposure to an FDA-regulated product has been received by the agency.
4. Office of Special Health Issues: OSHI will disseminate any public alerts related to the cargo theft to patients, practitioners, and institutions, as appropriate.

5. AGENCY-WIDE PROCEDURES

- A. The agency recipient (other than OCI) of a cargo theft report will immediately notify OCI Headquarters.
- B. When OCI receives a report that a cargo theft has occurred, OCI Headquarters will immediately contact the firm to verify that a theft has occurred and obtain the following information (including, but not limited to):
 - location of the theft
 - identity of the stolen product identity of the stolen product - (name of the stolen product(s), strength(s), dosage information, lot#(s), expiration dates(s), NDC#(s), package description
 - quantity of each stolen product
 - quantity of related lot(s) currently in legitimate distribution
 - storage requirements
 - Contact information for the firm representative(s) who are authorized to discuss product removal from the market, public notification etc.

OCI Headquarters will then immediately convey this information to the CTRT via e-mail to the CTRT notification/distribution list.

- C. Upon notification from OCI Headquarters of a cargo theft, OE will immediately contact the District where the responsible firm's headquarters is located and provide guidance to the District on the procedures to follow for contacting the firm and obtaining the firm's action plan regarding the cargo theft, especially with respect to any planned public notification or product removal from the market, if appropriate. The CTRT will develop general guidelines for the District when communicating with the firm and for public notification of the cargo theft.

Upon receipt of this information from the District, OE will forward the firm's action and other pertinent information to the CTRT. If any member of the CTRT expresses concern about the firm's action plan, OE will schedule a conference call for the CTRT to discuss those concerns. Representatives of the Center(s) that regulate the stolen product will assure that the appropriate experts from the Center(s) are available to evaluate the risk to the public health from a particular cargo theft. The CTRT will then determine whether a firm's action plan adequately addresses the public health risk posed by the cargo theft. If there is disagreement among the CTRT about the adequacy of the firm's action plan, then the issue will be brought to the appropriate Office directors for resolution.

- D. If the CTRT determines that the firm's action plan does not adequately address the public health risk, the District will communicate the CTRT's concerns to the firm within 24 hours of the CTRT's notification to the District. The District will inform the CTRT of the firm's response. In the event the CTRT is not satisfied with the firm's response, or the firm declines to take any action to address the public health risk, the CTRT will develop an appropriate regulatory response which may include the issuance of an FDA Consumer Alert, a notice to the members of the supply chain under paragraph G of this section, or other type of notice.

When evaluating the type and extent of public notification of the incident (whether by FDA or the firm), the CTRT shall consider factors that include, but are not limited to:

- Type of product stolen - finished product, bulk product, or sample etc.
- Storage and handling requirements for the product(s)
- Dosage form Dosage form - injectable, liquid, pill

- How much of the stolen lot was legitimately distributed before the cargo theft
 - Tampering protections in product packaging
 - Risk posed by the products if mishandled
 - Potential for the product to reenter the legitimate supply chain
 - Mitigating factors and steps taken by the company to specifically identify stolen lots or packages
 - Mitigating factors and steps taken by the company to prevent reentry into the supply chain
- E. If the CTRT determines that an FDA Consumer Alert or other type of notice is necessary (e.g. the firm refuses to notify the public of the cargo theft or the firm issues a press release that does not adequately inform the public about the public health risks associated with using the stolen product), the CTRT will work with the press office in the Office of Public Affairs (OPA) and the appropriate Center(s) to draft a press release and to obtain the necessary clearance from the agency and the Department of Health and Human Services (HHS). Public notification directed to practitioners and institutions will also be considered.
- F. The CTRT will work with the Office of International Programs (OIP) if the CTRT determines that foreign regulators should be notified about the theft. OIP will communicate the information to its foreign contacts.
- G. The CTRT will work with DIOP to provide for adequate screening of import shipments and coordinate appropriate evaluation, testing, or examination of suspect shipments.
- H. After receiving notice of a cargo theft, OE will work with appropriate Centers to draft a notice to wholesale distributors, retailers, and their professional associations of the cargo theft for dissemination through the communication network created to provide such notice.
- I. Currently established processes will be used to obtain appropriate clearance for issuance of any FDA notifications or alerts associated with cargo theft. OCI maintains a webpage of any press releases, and FDA notifications or alerts associated with significant cargo thefts that were issued, <http://www.fda.gov/ICECI/CriminalInvestigations/ucm182888.htm>.

The CTRT will work with the appropriate Center to identify a single point of contact to respond to inquiries from consumers, regulated industry, and other stakeholders (other than the news media).

6. EFFECTIVE DATE

The SOP is effective immediately upon acceptance by the Associate Commissioner for Regulatory Affairs.

7. Document History - SMG 9002.1, FDA's Response to Cargo Thefts

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/23/2012	N/a	ORA/OE	Dara Corrigan, Associate Commissioner for Regulatory Affairs

APPENDIX A - Cargo Theft Response Team (CTRT)

CBER	Office of Compliance: Director of Division of Case Management
CDER	Office of Compliance, Office of Drug Integrity Security & Recalls: Division of Supply Chain Integrity
CDRH	Office of Compliance: Special Assistants (2) to the Office Director
CFSAN	Office of Compliance: Director of Division of Enforcement and Labeling and Dietary Supplement Compliance Team Leader
CTP	Office of Compliance: Deputy Director
DIOP	The ORA DIOP Directors Group (ORA HQ DIOP Director GRP)
ORA/OCI	Cargo Theft Coordinators
OIP	Director of Office of Global Engagement
OPA	Team leader for Foods and Cosmetics
ORA/OE	Office of Enforcement: Emergency Coordinator
CVM	Director of Compliance