

Best Practices for the Prevention of Cargo and Warehouse Theft of FDA-Regulated Medical Products and Infant Formula

May 13, 2011

Hilton Washington DC/Rockville Hotel & Executive Meeting Center, Rockville, MD, USA



Stay One Step Ahead When Securing Your Warehouse and Product Transport.

Cargo and warehouse theft of FDA-regulated products, including prescription and over-the-counter medicines, vaccines, medical devices, and infant formula, poses a significant public health risk. Patients have experienced adverse reactions as a result of ingesting stolen drugs, reactions most likely due to improper storage and handling. Firms engaged in providing medical products and infant formula to the public need to be prepared to respond effectively when a cargo theft has occurred including a plan to quickly assess the type and amount of product stolen, the potential public health risk presented by the stolen product, and prompt public notification of the theft.

Various organizations have developed best practices and other guidance on how to prevent and respond to cargo and warehouse thefts. This meeting will discuss current best practices to ensure progress in reducing the number of cargo thefts by enhancing storage and in-transit security practices and providing a prompt and effective response when a cargo theft occurs.

FEATURED TOPICS

- Best Practices for the Prevention of Cargo and Warehouse Theft of FDA-regulated Medical Products and Infant Formula
- Supply-chain Security Vulnerabilities
- Regulatory Considerations and Oversight by the Office of Criminal Investigations
- Lessons Learned Following Theft during a Transport or at a Warehouse of FDA-Regulated Products
- Cooperation between FDA and Stakeholders

WHO SHOULD ATTEND

This program has been designed for senior-level management of manufacturing and distribution, law enforcement, wholesalers, transportation companies, logistics and security providers, insurance companies, and federal, state and local regulators.

PROGRAM CHAIRPERSON

Ilisa Bernstein

Deputy Director, Office of Compliance, Center for Drug Evaluation & Research (CDER), FDA

PROGRAM COMMITTEE

Rene Amaguana

Consumer Safety Officer, Center for Food Safety and Applied Nutrition (CFSAN), FDA

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Consumer Safety Officer/Pharmacist, Center for Drug Evaluation & Research (CDER), FDA

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Senior Operations Manager, Office of Criminal Investigations (OCI), FDA

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CONTINUING EDUCATION CREDITS



The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. (703) 506-3275.

DIA is authorized by IACET to offer .7 CEUs for this program.

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Disclosure Policy

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

LEARNING OBJECTIVES At the conclusion of this meeting, participants should be able to:

- Describe potential best practice strategies for the prevention and response to cargo/warehouse thefts
- Outline potential processes and procedures to reduce the number of cargo and warehouse thefts through enhanced storage and in-transit security practices
- Discuss effective responses when a cargo theft has occurred including a plan to quickly assess the type and amount of product stolen, the potential public health risk presented by the stolen product, and prompt public notification of the theft

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

DAY 1 | MAY 13, 2011

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45 AM WELCOME AND OPENING REMARKS

Speaker Invited

8:45-9:15 AM SESSION 1

Responding to Cargo Thefts: An FDA/OCI Perspective

This session will highlight FDA's response to the increase in cargo and warehouse thefts of FDA-regulated products, including prescription drugs and infant formula, and how supply chain vulnerabilities impact the cargo theft issue.

Gregg Goneconto

Special Agent, Senior Operations Manager
Office of Criminal Investigations (OCI), FDA

9:15-9:55 AM SESSION 2

Protecting Pharmaceutical Goods in Storage and In-Transit: Trends Identified in Theft Activity 2008-2011

This session will examine trends in pharmaceutical supply chain disruptions due to in-transit thefts and warehouse burglaries. It will also discuss the industry's improving relationships with law enforcement and risk management entities.

Charles Forsaith

Corporate Director, Supply Chain Security
Purdue Pharma Technologies Inc.

9:55-10:15 AM SESSION 3

Security Requirements/Regulations Impacting the Trucking Industry

The trucking industry plays an essential role in today's international and domestic supply chains. Trucks deliver cargo to and from factories, farmers, retailers, intermodal hubs, homes, hospitals, military installations, across borders, etc. This has resulted in a myriad of specific requirements on these operations, including heightened security since the 9/11 attacks. But trucking security has been a con-

cern prior to 9/11 due to cargo theft. This session will discuss how the trucking industry continues to develop and implement security initiatives to stay ahead of the bad guys.

Martin Rojas

Vice President, Security & Operations
American Trucking Associations

10:15-10:30 AM REFRESHMENT BREAK

10:30-11:00 AM SESSION 4

Cargo Theft Incident Response

This session will focus on response efforts.

Wendy LaRoche

Head Of Quality
Dermatologicals and US Market Supply Assurance
GlaxoSmithKline

Brian Goldsworthy

Director of Corporate Security - Americas
GlaxoSmithKline

11:00-11:30 AM SESSION 5

Partnering to Secure the Supply Chain

Productive internal and external partnerships are essential elements of supply chain security. Through these partnerships the security of the supply chain must be constantly monitored to stay ahead of both existing and emerging risks. This session will offer some helpful suggestions that should be considered in securing company owned and third party warehouses.

Robert M. Reilley

Chief Security Officer
Eli Lilly and Company

11:30 AM-12:00 PM SESSION 6

Supply Chain Security Vulnerabilities for Infant Formula

Robert Rankin

Associate Director
International Formula Council

12:00-1:30 PM LUNCHEON

1:30-2:30 PM SESSION 7

Best Practices for the Prevention of Cargo and Warehouse Theft

This session will facilitate the sharing of best practices specific to security of cargo during transport as well as warehouse security. Participants will hear firsthand from stakeholders, such as Pharmaceutical Cargo Security Coalition (PCSC), Rx360 & Consumer Healthcare Products Association (CHPA), about lessons learned and mechanisms proposed to prevent future warehouse and cargo thefts.

MODERATOR:

Ilisa B.G. Bernstein, PharmD, JD

Deputy Director, Office of Compliance
Center for Drug Evaluation and Research (CDER), FDA

PANEL:

Charles Forsaith

Corporate Director, Supply Chain Security
Purdue Pharma Technologies Inc.
Chairman, PCSC

Martin VanTrieste

Amgen SVP Quality &
Member Rx-360 Board of Directors

John Herzig

Vice President
Bayer HealthCare
Distribution and Logistics
Customer Logistics Service Center (CLSC)
Chair, Logistics Steering Committee, CHPA

2:30-2:45 PM REFRESHMENT BREAK

2:45-4:45 PM SESSION 8

Panel Discussion

4:45-5:00 PM CLOSING REMARKS

Deborah Autor, JD

Director of the Office of Compliance
Center for Drug Evaluation and Research (CDER), FDA

5:00 PM WORKSHOP ADJOURNED

REGISTRATION FORM

Register online or fax this page to +1.215.442.6199

DIA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

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Rockville, MD, USA

Registration Fees

Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

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BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

Contact Information

Event Information: Contact Joanne Wallace at the DIA office by telephone 215.442.6180, fax 215.293.5931 or email Joanne.Wallace@diahome.org.

TRAVEL AND HOTEL The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible. The Hilton Washington DC/Rockville Hotel & Executive Meeting Center is holding a block of rooms at the reduced rate below until April 21, 2011, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$189

Double \$189

Attendees must make their own hotel reservations. Contact the Hilton Washington DC/Rockville Hotel & Executive Meeting Center by telephone at +1.301.468.1100 and mention the DIA event. The hotel is located at 1750 Rockville Pike, Rockville, MD 20852, USA.

CANCELLATION POLICY: On or before MAY 6, 2011

Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200

Government or Academia or Nonprofit (Member or Nonmember) = \$100

Tutorial (if applicable) = \$50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

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