Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be construed to represent FDA’s view or policies.
Objectives

1. Identify FDA resources that contain information on the drug safety issues

2. Locate adverse event reporting information on FDA’s website

3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives
**FDA: What We Do**

- **Mission:** Promote and protect public health

- FDA’s primary responsibility is to protect the American people from unsafe or mislabeled food, drugs, and other medical products and to make sure consumers have access to accurate, science-based information about the products they need and rely on every day.

- **FDA/CDER** (Center for Drug Evaluation and Research) ensures that safe, effective and high quality drugs are available for U.S. consumers.
CDER/Office of Communications

Center for Drug Evaluation and Research

Office of Communications

Division of Online Communications
Division of Health Communications
Division of Drug Information
Division of Drug Information (DDI)

• DDI is CDER’s focal point for public inquiries regarding human drug products

• The **mission** of DDI is to optimize CDER's educational and communication efforts to our global community

• We support the FDA’s mission to promote and protect public health
# DDI Inquiries

<table>
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<tr>
<th>Point of Contact</th>
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<td>Emails</td>
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<td><strong>Grand Total</strong></td>
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![Graph showing trends from 2008 to 2015]

- After Hours, Live Calls, and Voicemails
- Emails
- Letters
DDI International Inquiries
FDA’s Global Presence

• 300,000 foreign facilities from more than 150 countries export FDA-regulated products to the United States

• 40 percent of listed finished drugs are imported

• Imported medical devices constitute over 35 percent of the U.S. medical equipment market

• There are myriad opportunities for drug products to be improperly formulated or packaged, contaminated, diverted, counterfeited or adulterated
FDA’s Global Presence
Office of Regulatory Affairs (ORA)

About the Office of Regulatory Affairs

The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its mission, ORA also works with its state, local, tribal, territorial and foreign counterparts.

ORA News

- Federal court orders Alabama seafood company to cease
ORA FOIA Electronic Reading Room

- Obtain copies of ORA records
  - 483 inspection reports/response
  - FDA requested recall letter
  - Establishment Inspection reports
- Pharmacy Inspection reports
- Contact information to district ORA offices
- FOIA request

FOIA, Freedom of Information Act
The ORA Electronic Reading Room displays copies of ORA records. We are making these records publicly available either (1) proactively at our discretion or (2) because they are “frequently requested” per the Electronic Freedom of Information Act Amendments of 1996. Some records may be redacted to remove non-public information (see 21 CFR Part 20). For other ORA documents, please visit the ORA home page and the FDA Warning Letter page for other FDA documents, please visit the FDA Freedom of Information (FOI) page.

RSS Feed for ORA FOIA Electronic Reading Room [what's this?]

Filter by Record Type:

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Clear Filters
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRIBUTION ADDRESS AND PHONE NUMBER
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax: (407)475-4768

DATE OF INSPECTION 7/18/2016-7/29/2016

.fadeout, .highlight, .boxed {background-color: #FF0000; color: #FFFFFF; border: 3px solid #FF0000; padding: 10px; display: block; box-shadow: 0 0 10px #FF0000; }

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED:
Ponswamy Rajalingam, President & Owner

FAX NUMBER 3011319445

STREET ADDRESS 1015 W Newport Center Dr Ste 106A

OUTSOURCING FACILITY

CITY, STATE ZIP CODE COUNTRY Deerfield Beach, FL 33442-7707

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

a. A review of media fills conducted between 10/15/2015 and 04/2016 revealed that the media fills were not representative of actual production processes in that the media fills failed to simulate a lot with the maximum number of vials. The maximum vials observed in the media fill were [redacted] vials. Your firm has filled the following:
   i. Cyanocobalamin 1000mcg/mL, lot #01PJ1: [redacted] vials
   ii. Cyanocobalamin 1000mcg/mL, lot #03PM01: [redacted] vials
   iii. Methylcobalamin 1mg/mL, lot #05PM12: [redacted] vials
   iv. Methylcobalamin 1mg/mL, lot #03PM15: [redacted] vials and [redacted] vials

b. Your firm has not validated your [redacted] for the depyrogenation of glassware and amber vials used in the production of sterile injectable drug products.
Medication Safety
Report:
• Adverse events
• Product problems
• Product use errors

Forms:
Voluntary
• Form FDA 3500
• Form FDA 3500 B

Mandatory
• Form FDA 3500 A
Drug Safety Communications (DSC)

CDER’s primary tool for communicating important new and emerging safety information to the public

- New drug warnings
- Drug label changes
- Other safety information
Medication Guides

- Prevent serious adverse effects
- Assist with informed patient decision making
- Information for patient adherence to directions for use of a product
Medication Errors

Division of Medication Error Prevention and Analysis (DMEPA) reviews:

• Medication error reports on marketed human drugs including prescription drugs, generic drugs, and OTC drugs

• MedWatch Reports

• Proprietary names, labeling, packaging, and product design prior to drug approval to help prevent medication errors
Drug Shortages
Drug Shortages

Search the Drug Shortages Database

Upgraded Drug Shortages app for Android devices adds alert feature

The Food and Drug Administration released Drug Shortages 2 mobile application for Android devices. Android device users are able to receive notifications when there is new or updated information about a shortage of a drug product or about a drug within selected therapeutic categories.

Designed for Android devices, Drug Shortages 2 sends alerts when the Agency adds or updates shortage information about a drug product or about a drug within selected therapeutic categories. We are currently working on notifications for the iOS version of the Drug Shortage mobile app, which will be available soon.

Download the Drug Shortages 2 app for Android devices

Download the Drug Shortages Mobile Application

Download on the App Store  
Download on Google Play
Drug Shortages Mobile App
Drug Shortage Data

Drug Shortages: New vs Prevented

Number of Drug Shortages

- FY 2010: 178
- FY 2011: 251
- FY 2012: 117 (PREVENTED)
- FY 2013: 44 (NEW), 170 (PREVENTED)
- FY 2014: 44 (NEW), 101 (PREVENTED)
- FY 2015: 26 (NEW), 142 (PREVENTED)
Reasons for Drug Shortages

- Quality Manufacturing: 37%
- Raw Materials: 27%
- Loss of MFG Site: 2%
- Increased Demand: 5%
- Discontinuation: 2%
Responding to Drug Shortages

• Regulatory Discretion
  • Allows for manufacture of medically necessary products to continue
  • May require additional safety controls
    • Filters with product; extra testing at plant; 3rd party oversight of production; special instructions for safe use

• Request other firms to raise production

• Expedite reviews
  • New manufacturing sites, longer expiry date, new raw material source, changes in specifications, etc.

• In rare cases, temporary importation from unapproved sources
Recalls

The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See Additional information about recalls for a more complete listing.

For recall notices older than 60 days, see the Recall and Safety Alerts Archive.

Sign up to receive Recalls, Market Withdrawals and Safety Alerts.

Filter by Keyword(s):

Filter by Recall Type:

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<th>Brand Name</th>
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<td>French Toast with diced potatoes and mandarin oranges</td>
<td>Undeclared Milk</td>
<td>Granna's LLC</td>
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Enforcement Reports

All recalls monitored by FDA are included in the Enforcement Report once they are classified. Information about how to navigate the report and for definitions of the report labels are found on the Enforcement Report Navigation and Definitions page.

For information gathered from press releases and other public notices about certain recalls of FDA-regulated products you can visit Recalls, Market Withdrawals, & Safety Alerts.

FDA is conducting two pilot programs to expedite notifications of Non-Blood (HCT/P, Vaccine, Derivative, etc.) and human drug product recalls to the public which can be found in the below links:

- Human Drug Product Recalls Pending Classification (also available by selecting "Pending Recalls")
- Non-Blood Product On-Going Recalls

To subscribe to the enforcement report mailing list please follow this link: Enforcement Report email subscription.

Please e-mail enforcementreports@fda.hhs.gov with any comments.
Enforcement Reports

All recalls go into FDA's Enforcement Report once they are classified according to the level of hazard involved.
Labeling Initiatives
Get email alerts when the site changes

Download historic REMS data in CSV format

Search by REMS, drug name, and element

Sort to find the most recently updated REMS

Click for more detailed info on each REMS

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## Approved Risk Evaluation and Mitigation Strategies (REMS)

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) for manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

The table below provides links to currently approved individual and shared system REMS.

Information on historical and released REMS: [downloadable data files](#).

Filter by Keyword (e.g., REMS name, active ingredient, element):

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<th>Name</th>
<th>Last Updated</th>
<th>Medication Guide*</th>
<th>Communication Plan</th>
<th>ETASU</th>
<th>Implementation System</th>
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</table>

* Medication Guide available for some REMS.
What do participants need to know?

Below is a general overview of the REMS for all REMS participants (e.g., patients, pharmacies, and healthcare providers). See the product-specific REMS website or the approved REMS materials for more information.

Go to application holder’s REMS website

- Healthcare Providers who prescribe isotretinoin products must
- Patients who are prescribed isotretinoin products
- Pharmacies that dispense isotretinoin products must

View requirements for each participant
### REMS: Information for HCPs

**Healthcare Providers who prescribe isotretinoin products must**
- Designate an authorized representative to carry out the certification process on behalf of the pharmacy.
- Have the authorized representative enroll in the REMS by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.

**Patients who are prescribed isotretinoin products**
- Provide the patient with the Medication Guide.
- Obtain authorization to dispense by contacting the iPLEDGE Program via web or voice-based system. Document the Risk Management Authorization (RMA) number on the prescription.
- Dispense prior to the “do not dispense to a patient after” date provided by the iPLEDGE Program.
- Dispense no more than a 30 days’ supply.
- Do not dispense refills.

**Pharmacies that dispense isotretinoin products must**
- Re-enroll in the iPLEDGE Program.

**To be able to dispense**
- Return unused product to the manufacturer.
- Do not distribute, transfer, loan, or sell product.

**Before dispensing**
- Designate an authorized representative to carry out the certification process on behalf of the pharmacy.
- Have the authorized representative enroll in the REMS by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.

**Every year**
- Provide the patient with the Medication Guide.
- Obtain authorization to dispense by contacting the iPLEDGE Program via web or voice-based system. Document the Risk Management Authorization (RMA) number on the prescription.
- Dispense prior to the “do not dispense to a patient after” date provided by the iPLEDGE Program.
- Dispense no more than a 30 days’ supply.
- Do not dispense refills.

**At all times**
- Return unused product to the manufacturer.
- Do not distribute, transfer, loan, or sell product.
Comparison of current prescription drug labeling with the PLLR new labeling requirements

Pregnancy and Lactation Labeling Rule (PLLR)

- PLLR requires content and format changes for information presented in prescription drug labeling.
- Changes intended to assist health care providers in assessing benefit versus risk, assist with counseling.
- Allows women/mothers to make informed and educated decisions for themselves and their children.
- PLLR removes pregnancy letter categories – A, B, C, D and X.
- PLLR requires the label to be updated when information becomes outdated.

Additional Resources

• CDER Home Page

• Drug Information Resources
CDER Home Page: Where to Find Resources
FDA Databases/Resources

- Drugs @FDA
- NDC Directory
- Orange Book
- Purple Book
- Drug Safety Labeling Changes (SLC) Database
- Drug Shortages
- Approved Risk Evaluation and Mitigation Strategies (REMS)
- Drug Safety Communications
- MedWatch
CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA) WEBINAR SERIES

Submitting REMS in structured product labeling (SPL) format
What you need to know - August 24, 2016

Resources for You
For Consumers, Health Professionals, Industry
The “Purple Book” includes:

• A list of biological products, including any biosimilar and interchangeable biological products

• The date a biological product was licensed and whether FDA evaluated the biological product for reference product exclusivity

• Indicates whether a biological product has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product

• Biosimilar and interchangeable biological products licensed will be listed under the reference product to which biosimilarity or interchangeability was demonstrated

• Separate lists for those biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER)
The Drug Safety Labeling Changes (SLC) database provides approved safety labeling changes from January 2016 forward. Data prior to January 2016 will continue to be available on the MedWatch website.

Additional information and resources for drug safety labeling.

There are two ways to search: a Drug Name Search and a Date Search.

**Drug Name Search**

Drug Name or Active Ingredient: Enter at least 3 characters

Search  Reset

**Date Search**

For Safety Labeling Changes before January 1, 2016 see the MedWatch Safety Labeling Page

Date Range: 01/01/2016 09/02/2016

Labeling Section:
- Boxed Warning
- Contraindications
- Adverse Reactions
- Warnings and Precautions
- Drug Interactions
- Use in Specific Populations
- PCI/PI/IMG (Patient Counseling Information/Patient Information/Medication Guide)

Search  Reset

- Provides approved safety labeling changes from January 2016 forward
- Data prior to January 2016 will continue to be available on the MedWatch website
SLC Database Search

How to Search Within Results / Choose Result
Search within multiple results, filter results, sort by column, or select drug name.

How to Download Data Files
Search results can be downloaded and saved in CSV format.

Drug Safety Labeling Changes (SLC)

Click here to download the approved drug labeling.

Boxed Warnings

WARNINGS: DRUG PRODUCT CAN INCREASE THE RISK OF CARDIOVASCULAR EVENTS

Contraindications
Concurrent use of DRUG PRODUCT with other nephrotoxic drugs should be avoided

Warnings and Precautions
Hepatic impairment can potentiate the response to DRUG PRODUCT and decrease its metabolism. Use DRUG PRODUCT with caution in these patients

Adverse Reactions
DRUG PRODUCT can cause nausea, vomiting and/or gastrointestinal distress

Click here to download data in a CSV file.
Other DDI Resources

- DDI website: http://www.fda.gov/AboutDDI
- CDER Mailing List: http://www.fda.gov/aboutfda/contactfda/ucm2005606.htm
- FDA Drug Info Rounds: http://www.fda.gov/DrugInfoRounds
- CDERLearn: http://www.fda.gov/training/forhealthprofessionals/default.htm
- Facebook: https://www.facebook.com/FDA
- Twitter: https://twitter.com/FDA_Drug_Info
- LinkedIn: https://www.linkedin.com/company/10803751
- DDI Webinars for HCPs: http://www.fda.gov/DDIWebinars
- Student, Fellowship, and Senior Scientist Programs: http://www.fda.gov/PharmStudentProgram and http://www.fda.gov/RegPharmFellowship
Which drug information resource can you use to find the FDA-approved indications for a drug?

A. Orange Book
B. Drugs@FDA
C. Purple Book
D. Google it
True or False: The new Pregnancy and Lactation Labeling Rule (PLLR) includes information, when necessary, about the need for pregnancy testing, contraception recommendations, and information about infertility as it relates to the use of the drug?

A. True

B. False
QUESTIONS?

Contact DDI:
DDI Phone: 855-543-3784 or 301-796-3400
Email: druginfo@fda.hhs.gov