

**ITCBA Seminar
October 15, 2009**

**Robert Rodriguez
Cincinnati District FDA
513-679-2700
robert.rodriguez@fda.hhs.gov**

FDA's Mission

The Food and Drug Administration (FDA) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws which are designed to protect consumers' health, safety, and pocketbook. These laws apply equally to domestic and imported products.

Import's Mission

With the exception of most meat and poultry, all food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation, as defined in the FD&C and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States. Most meat and poultry products are regulated by the U.S. Department of Agriculture.

Imports

All imported products are required to meet the same standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions; drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.

FDA Regulated Products

- Foods
- Animal feed
- Drugs
- Medical Devices
- Biologics
- Cosmetics
- Electronic Products that Emit Radiation

How does the system work?

FDA is notified electronically the majority of the time when a shipment is offered for entry into the United States through OASIS, **O**perational and **A**dministrative **S**ystem for **I**mport **S**upport .

Mandatory OASIS Fields

- Product Description
- Manufacturer
- Shipper
- Country of Origin
- FDA Product Code

If the entry reviewer finds a problem
they can:

- Ask for documents.
- Schedule the product for a field examination.
- Schedule the product for sampling.
- Request a Detention

If an Entry Reviewer asks for documents it means:

The Filer/Broker is to fax the 3461/7501, invoice, Bill of Lading and any other additional information.

Detention

Based on the appearance” clause in Section 801, the product can be detained until the problem is solved or if the product is on Import Alert

Common Errors

When using RB1 as the AofC put in the Accession number, not the Model #. This is a very common error. It results in a request for documents for an entry which would have been may proceeded if the AofC had been used correctly.

Common Errors

- Incorrect NDC # for firm with multiple ones.
- No registration number or 510K for manufacturer and/or consignee
- Incorrect spelling of manufacturer and/or consignee.
- No dollar value amount declared for the shipment.
- Manufacturer and/or consignee does not match with docs - reviewer must take time to change the information.
- The lack of the above information causes reviewer to request docs; thus, it takes longer to release the shipment.

What's New

- PREDICT
- ITACS
- Tobacco

SUMMARY

- CBP owns entry processing.
- FDA regulates products and can act against the product wherever it is.
- FDA's guidance does exist, but some of it is dated and always under constant review.

Web Sites

- FDA's HOME PAGE - www.fda.gov
- FDA IMPORT FOOD INFORMATION - www.fda.gov/ora/import
- WEB BASED PRODUCT CODE BUILDER - www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm
- IMPORT ALERTS - www.fda.gov/ora/orasrch.htm

Disclaimer

Code of Federal Regulations title 21 sec 10.85

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Questions

