Imported Food and Medical Products Compliance

FDA Office of Regulatory Affairs
Office Of Enforcement and Import Operations
Division of Southeast Imports
June 24, 2019

Per 21 C.F.R. 10.85(k), information in this presentation is an informal communication that represents my best judgment 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.

Key Import Systems

Two of FDA's electronic systems, Import Entry Review and Operational and Administrative System for Import Support (OASIS), in combination with a screening tool called Predictive Risk Based Evaluation for Dynamic Import Compliance Targeting (PREDICT), expedite the import review process by helping FDA reviewers evaluate the declared information.

Import Operations

- Admissibility of regulated products
- Field Examinations
- Sample Collections
- Filer evaluations
- Inspections
- Collaboration with other government agencies and industry

Import Compliance Branch

- Detention & Hearing
- Reconditioning
- Refusals
- Import Alerts
- Compliance assignments
- FDA & CBP Enforcement Actions
- Outreach

Importations

- Covered by the Federal Food Drug & Cosmetic Act (section 801)
- 801(a): Allows for refusal of imported FDA-regulated products for appearing to be adulterated or misbranded based on evidence
- 536(a): Allows for refusal of imported electronic products for appearing to fail to comply with an applicable standard

Importations

Key Statutory Provision Section

Under 801 (a) of the FD&C Act

" The secretary of the Treasury shall deliver to the Secretary of the Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics, which are being imported or offered for import into the United States…"

Practical Application:

- -This section confers the right to collect import samples.
- - MOU was signed by FDA (representing DHHS) and Customs (representing the Treasury) delegating the authority to examine and collect products in Import status to FDA.

Importations

- with notice of such delivery to the **owner or consignee**, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony.
- or the **importer** (as defined in section 384a of this title)

Importer defined under FSMA..

- **IMPORTER DEFINED** For purposes of this section, the term "importer" means, with respect to an article of food—

(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

- **Section 801 of the FD&CA**

"If it appears from the examination of such samples *or otherwise* that…"

(1) such article has been manufactured, processed, or packed under insanitary conditions… or

(2) such article is forbidden or restricted in sale in the country in which it was produced … or

(3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)

"then such article shall be refused admission…"

Importations

"appears" – provides FDA's standard of proof

- We can refuse entry to goods that:
  - Appear to be adulterated or misbranded
  - Appear to be unapproved new drugs
  - Appear to have been manufactured not in accordance with GMPs

Importations

"or otherwise" – allows FDA to make admissibility decisions using:

- Historical data
- Examinations (vs. sample collections)
- Information from other sources
- Other evidence

Importations

- Under 801 (b) of the FD&C Act

"Pending decision as to the admission of an article being imported or offered for import, the Secretary of the treasury may authorize delivery to the owner or consignee upon the execution… of a good and sufficient bond providing for the payment of…liquidated damages in the event of default"

Practical Application: This provision authorizes Customs to permit the article to move to destination awaiting release by FDA. The owner or consignee must post a bond and it should be **sufficient**.

Importations

- Section 801 also requires that products of foreign origin in import status must be held intact until FDA has determined the admissibility of the shipment.

Importations

Upon entry, FDA will decide to:

- Release the goods
- Detain the goods without exam
  - Based on submission of required information
  - Based on import alerts
- Obtain more information:
  - Through Documents
  - Through Examination and/or Sample Collection

Importations

If Released……

- Product may be distributed
- FDA still has jurisdiction
- Does not preclude FDA action if a problem is found later

Importations

REGARDLESS OF THE NATURE OF THE DETENTION:

- Importer has the right to give evidence to refute this appearance
  - This is known as the "Detention and Hearing Process"
- Based on the evidence, the detention will either stand (refusal) or be overturned (release)

Importations

- Importer can also petition to recondition the goods to bring them into compliance

  - ✓ Relabeling a misbranded product
  - ✓ Cleansing an adulterated product
  - ✓ Making a product not FDA regulated

- Reconditioning must be approved by FDA

Importations

- If a product cannot be brought into compliance, the product will be refused entry.
- If products are refused admission into the U.S. , the importer has 90 days to either:

A. Destroy the product.

B. Export the product.

Importations

- At the time of refusal, a redelivery notice is sent by CBP to the importer.
- A liquidated damages case is issued by CBP if the product is not exported or destroyed within the 90 days of refusal.

FDASIA…..Section 708

- The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, **except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less** (or such higher amount as the Secretary of the Treasury may set by regulation….

IMPORT ALERT SYSTEM

1. Certain Firms/Products are subject to DWPE (Detention Without Physical Examination) at the time of entry.

☞ **Violative history of:**

- ✓ Commodities
- ✓ Manufacturers/shippers
- ✓ Growers
- ✓ Geographic area
- ✓ Countries of origin
- ✓ Importers
- ✓ Or combinations of the above

Import Alerts

http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm

- Import Alerts:
  - Provides guidance to the field that we have sufficient evidence to detain goods without examination

Removing a firm/product from Import Alert

- Firms or importers may petition to be removed from DWPE
  - Industry submits the petition
  - FDA reviews the petition

- Generally requires evidence of non-violative shipments but all depends on the Import alert

  - Firms with GMP violations may need an inspection to get off an IA
  - Analyzed by laboratory at importer expense
  - Documentation showing it isn't subject to the Alert

- ✓ FDA needs assurance the cause of the violation has been corrected

U.S. FOOD & DRUG ADMINISTRATION

FDA Refusal of Admission

Refusal of Admission

Section 801(a) of the Federal, Food, Drug and Cosmetic Act directs the Secretary of the Treasury to issue a Notice of Refusal when it appears from examination of samples, or otherwise, that an imported shipment is in violation.

FDA can refuse admission if a regulated product:

- Has been produced under insanitary conditions or, for devices, produced without GMPs
- Is forbidden or restricted in sale in the country it was produced in or exported from
- Is adulterated, misbranded, or an unapproved new drug, device or combination product

- FDA can also refuse admission for:
  - Radiation emitting product on the grounds listed in Section 536(a) of the Act
  - Prescription human drug that is manufactured in a State, exported, and re-imported by an entity that is not the manufacturer (801(d))
  - Food for Prior Notice or Registration violations (801(l) and (m))
  - OTC human drug or dietary suppl. for adverse event reporting violations (801(a))

FDA can also refuse admission for:

- Drug and device for registration violations (801(o))
- FDA and CDC have authority to prevent the transmission of communicable diseases, including at importation (section 361 of the PHSA)
  - CDC generally has the lead
  - Governs tissue and HCT/P importation

When does FDA Issue a Refusal of Admission?

- A response to a Notice of Detention and Hearing is not received within the specified ten day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted.

- Efforts to relabel or recondition the detained shipment pursuant to an approved application (Form FD-766) have failed.

When does FDA Issue a Refusal of Admission?

- When a detained shipment has been reconditioned pursuant to an approved application (Form FD-766), and we have agreed to the exportation of the reject material, a Notice of Refusal of Admission is issued covering the rejects.

- After a hearing relative to the validity of the charges for detention, the hearing office rules that the charges are valid and a Form FD-766 has not been submitted.

- Upon written request by the Importer, owner or consignee.

Refusal under 801(a)

Under 801(a):

> "The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported . . . within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations."

FDA Refusal of Admission
CBP Demand for Redelivery

- FDA issues Notice of Refusal/CBP issues Demand for Redelivery

- Redeliver to Customs custody

Importer's options (within 90 days of refusal)

- Destruction
- Exportation

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
001/001	Ceramic Mug
Refused:	15,000 No.

FD&CA : 402(a)(1); 801(a)(3); Adulteration

The article is subject to refusal of admission pursuant to 801(a)(3) in that it appears to contain a poisonous or deleterious substance, lead, which may lend it injurious to health.

For the District Director of Customs:

Tammara D. Perry, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
959 Ridgeway Loop Road, Suite 100
Memphis, TN 38120-4042

(901) 333-3534
(901) 333-3579 (FAX)
Tammara.Perry@fda.hhs.gov

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

New Orleans CBP Office
1515 Poydras Street Suite 1700
New Orleans, LA 70112

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

FDA may witness the exportation or destruction of the refused merchandise jointly with CBP, or in lieu of CBP.

REFUSAL OF ADMISSION

REDELIVERY REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
001/001	[redacted] ARECA NUTS

Refused : 1,125 PCS

FD&CA Section 402(a)(1), 801(a)(3); ADULTERATION

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a poisonous or deleterious substance which may render the article injurious to health [Adulteration, Section 402(a)(1)]. Contains: betel nut (areca). Betel nut(areca) is not generally recognized as safe for use in conventional foods.

Notice of FDA Action
Entry Number: [redacted]

Notice Number: 3
Page: 2

For the District Director of Customs:

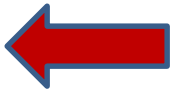
Jacquelyn Bradford, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
959 Ridgeway Loop Road, Suite 100
Memphis, TN 38120-4042

(901) 333-3520
(901) 333-3579 (FAX)
Jacquelyn.Bradford@fda.hhs.gov

A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:



CBP Memphis Port Office
3150 Tchulahoma Road, Suite 1
Memphis, TN 38118

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Documentation

Records that document exportation or destruction:

Exportation:
CF 7512 and Air bill/way bill/bill of lading for exporting vessel.

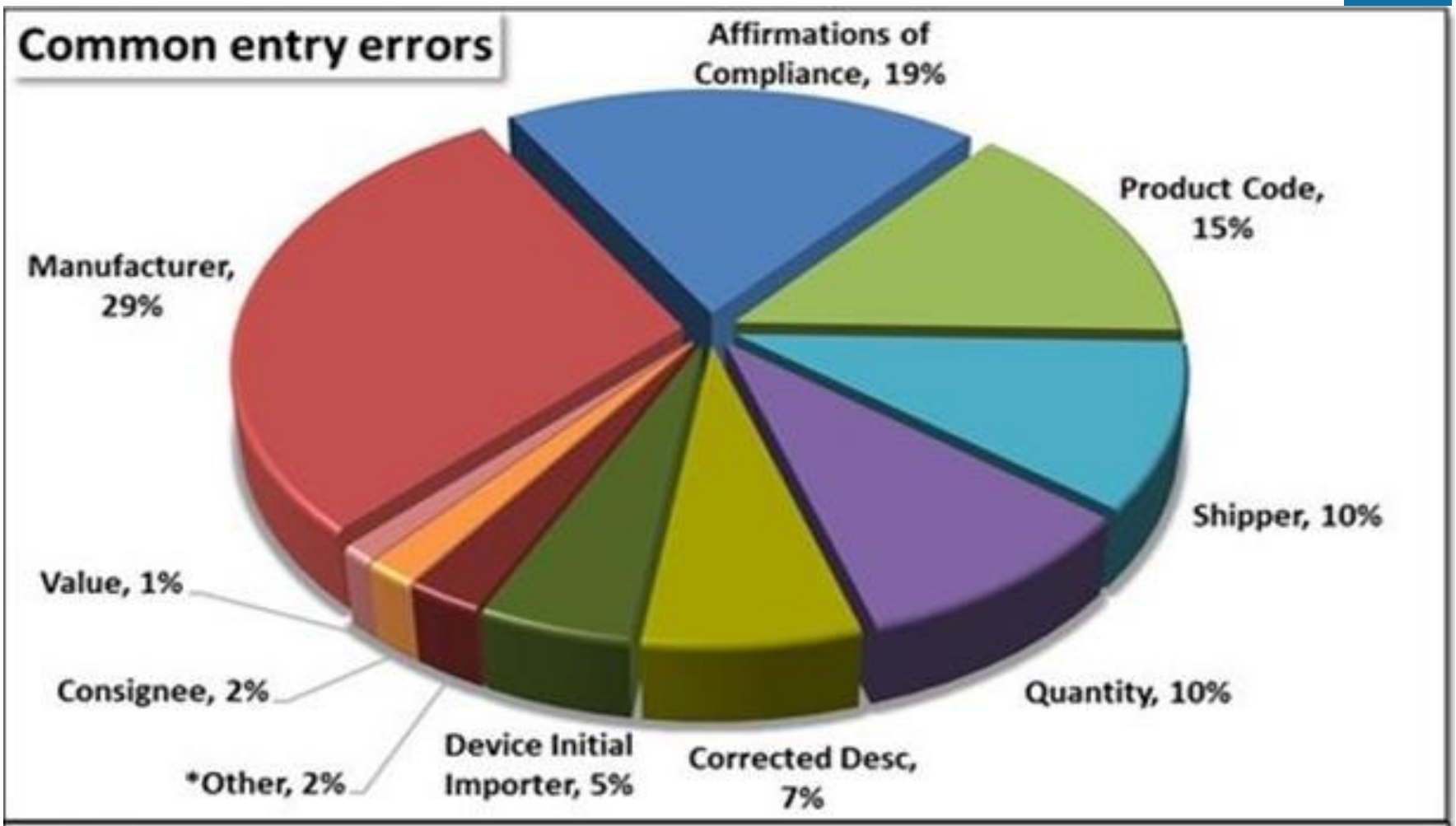
Destruction:
CF4607, CF4613, CF3499
(with CBP signature or FDA signature if witnessed by FDA in lieu of CBP).

Resources

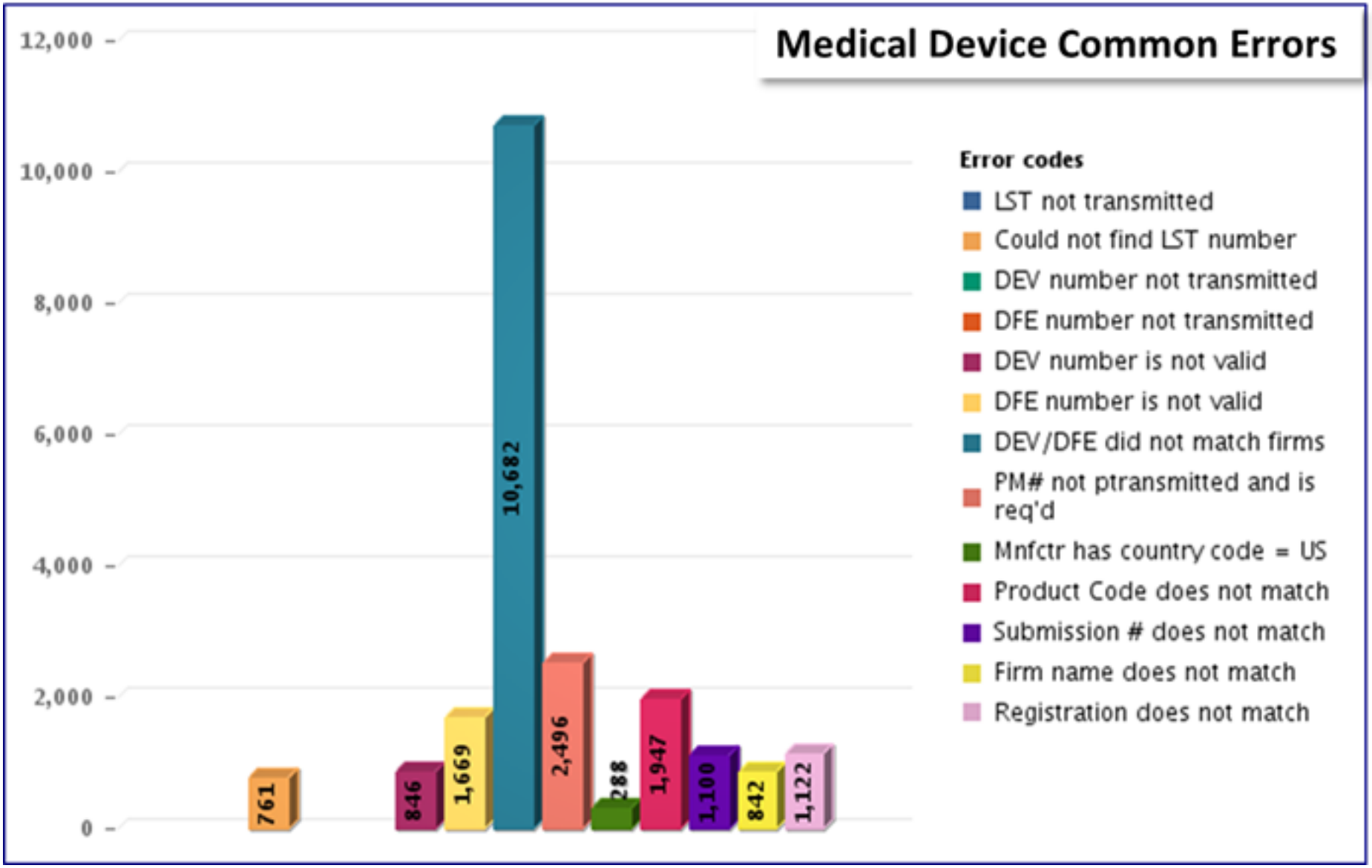
- www.fda.gov
- Federal Food, Drug, & Cosmetic Act
- Code of Federal Regulations, Titles 21 and 19
- RPM Chapter 9 at: www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9.html
- IOM Chapter 6 at: www.fda.gov/ora/inspect_ref/iom

U.S. FOOD & DRUG ADMINISTRATION

Common Entry Errors and Medical Device entry stats



*Other
This category consists of the following error categories which each counted for less than 1% of all errors; Country of Production/Source/Growth, Importer, Country of Shipment, Container Dimensions, Intended Use Code, Active Ingredient Info, PG25 Lot Number


Medical Device Common Errors
12,000
10,000
8,000
6,000
4,000
2,000
0
761
846
1,669
10,682
2,496
288
1,947
1,100
842
1,122
Error codes
LST not transmitted
Could not find LST number
DEV number not transmitted
DFE number not transmitted
DEV number is not valid
DFE number is not valid
DEV/DFE did not match firms
PM# not ptransmitted and is req'd
Mnfctr has country code = US
Product Code does not match
Submission # does not match
Firm name does not match
Registration does not match

Common Errors in Drug Entries

- Incorrect Foreign Drug Manufacturer Site Address
- Listing, Approval and Registration Not Provided
- **Dosage Not Provided for Finished Dosage Imports**
- Incorrect IND Sponsor or None Provided
- Incorrect IND Drug Name or None Provided

Over The Counter Finished Dosages

- Must conform to an OTC Monograph or have an approved OTC NDA/ANDA
- Foreign Drug Manufacturer Registration
  - Foreign Drug Manufacturer must list all *Known Importers* in their registration
- Drug Listing

Investigational New Drugs

- For Human Use
- IND Application Must be Active
- IND Drug Name Must be Verified in the Entry
- IND Sponsor Must Appear in Entry Documents
  - Importer of Record or Consignee Must be Sponsor or Domestic Agent
- Active INDs are Exempt from Registration and Listing

Foreign Drug Firm Registration & Drug Listing

21 CFR 207

- All foreign firms that manufacture, prepare, propagate, compound, or process a drug imported or offered for import into the U.S. shall, through electronic means …
- Register the name and place of business
- Designate a U.S. Agent
- **Provide names of each known importer & person who imports or offers for import**
- List all drug products imported or offered for import into the U.S.

CDER Pre-Launch Activities Importation Requests (PLAIRs)

- FDA's policy to exercise enforcement discretion on the importation of a limited amount of an unapproved finished dosage form product in preparation for the market launch based upon anticipated approval
- Drug product must be in final packaged form or require only minimal further processing such as final packaging and/or labeling
- CDER-regulated NDA, ANDA or BLA
- CDER-OC-PLAIR@fda.hhs.gov
- If CDER grants the PLAIR then CDER notifies DIO
- Entry Reviewers verify pending approval and quantities

Personal Importation

- A personal importation is a product not for further sale or distribution into U.S. commerce. These products may be carried in baggage or shipped by courier or international mail.

Import for Export (IFE)

Allows Unapproved New Drugs to be Imported for Further Manufacturing and Re-exportation with

- A statement that article is intended to be further processed and that it will be exported under
  - sections 801(e) or 802 of the FD&C Act [21 U.S.C. 381 (e) or 382]
- Chain of Custody
  - Information to identify the manufacturer of the article and each processor, packer, distributor, or other entity in chain of possession from manufacturer to importer
- Certificates of Analysis
  - as necessary to identify the article

Tips for Importing Drug Products

Expedite FDA's Processing by Providing:

- Correct Product Code and Intended Use Code
- Active Ingredient Name and Dosage
- Brand Name
- Name, Address (and DUNS or FEI number if known) for:
  - Manufacturer, Shipper, Importer, Delivered To Party, and API Producer
- Affirmations of Compliance: (required based on Intended Use)
  - REG (Drug Registration)
  - DLS (Drug Listing)
  - DA (Drug Application Number: NDA, ANDA or BLA)
  - IND (Investigational New drug)

Find POC's for Import Divisions

FDA Internet Map and list of Contacts:

- https://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Contact a Local FDA Import Office

Division of Southeast Imports
(AK, AL, AR, FL, GA, KY, LA, MS, NC, SC, TN, PR, USVI, and portions of IN)

- To request information on general FDA import requirement specifics, see topics below or contact FDAImportsInquiry@fda.hhs.gov.
- To request the status on an entry, check ITACS first, then contact the port.

Regulated Product	Find Information about:

Customer Service

- ITACS for entry updates https://itacs.fda.gov
- Product code inquiries PCBFeedback@fda.hhs.gov
- Status of an entry – *FDA Import Offices and Ports of Entry*

Any Questions?

Tammara P. Threats

Director, Compliance Branch

Division of Southeast Imports

Office of Regulatory Affairs

U.S. Food and Drug Administration

T: 901-333-3534

Tammara.Threats@FDA.HHS.GOV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