FDA Import Operations Overview

Cindy Ford, Consumer Safety Officer
Division of Import Operations
Office of Enforcement and Import Operations
Office of Regulatory Affairs
June 2020
Presentation Overview

• General overview of U.S import operations
• Import Process/Screening
• Import Alerts/Detention Without Physical Exam (DWPE)
• Firm Registration
• Food Safety Modernization Act (FSMA)
  – Foreign Supplier Verification Program (FSVP)
  – Voluntary Qualified Importer Program (VQIP)
• Resources
FDA Imports Overview

IMPORT OPERATIONS
Import Program Divisions

FDA Import Offices and Ports of Entry: [https://www.fda.gov/forindustry/importprogram/ucm319216.htm](https://www.fda.gov/forindustry/importprogram/ucm319216.htm)
Regulated Products

Percentage of Imported Lines* by Commodity for Fiscal Year 2019

- **Devices**, 48%
- **Human Foods**, 31%
- **Radiological Health**, 3%
- **Housewares & Food-Related Items**, 8%
- **Cosmetics**, 6%
- **Drugs & Biologics**, 2%
- **Animal Feed**, 1%
- **Tobacco Products**, <1%
FY 2009 – 2019 Lines

Total Lines* of Products Imported into the U.S. per Fiscal Year

* The number of total lines imported into the U.S. per fiscal year from 2009 to 2019 shows a consistent increase, with a significant rise in the last few years.
FY 2014 – 2019 Entry Lines

Fiscal Year


Total Lines All Countries

32,565,280 34,527,350 36,990,477 40,018,795 43,606,426 45,194,561

Total Lines Fiji

8,106 8,185 8,665 9,048 8,986 8,512
## FY 2019 Lines by Category

<table>
<thead>
<tr>
<th>Category</th>
<th>All Countries</th>
<th>Fiji</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN FOODS</td>
<td>14,112,220</td>
<td>8,207</td>
</tr>
<tr>
<td>ANIMAL FEED</td>
<td>391,014</td>
<td>0</td>
</tr>
<tr>
<td>HOUSEWARES &amp; FOOD-RELATED ITEMS</td>
<td>3,629,738</td>
<td>9</td>
</tr>
<tr>
<td>COSMETICS</td>
<td>2,762,052</td>
<td>251</td>
</tr>
<tr>
<td>DRUGS &amp; BIOLOGICS</td>
<td>1,009,212</td>
<td>0</td>
</tr>
<tr>
<td>DEVICES</td>
<td>21,482,442</td>
<td>43</td>
</tr>
<tr>
<td>RADIOLOGICAL HEALTH</td>
<td>1,527,089</td>
<td>2</td>
</tr>
<tr>
<td>TOBACCO PRODUCTS</td>
<td>280,794</td>
<td>0</td>
</tr>
</tbody>
</table>
# FY 2019 Lines with Activities

<table>
<thead>
<tr>
<th></th>
<th>Lines Examined</th>
<th>Lines Sampled</th>
<th>Lines Refused</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Countries</td>
<td>Fiji</td>
<td>All Countries</td>
</tr>
<tr>
<td>Human Foods</td>
<td>89,140</td>
<td>18</td>
<td>13,353</td>
</tr>
<tr>
<td>Animal Feed</td>
<td>1,637</td>
<td>0</td>
<td>465</td>
</tr>
<tr>
<td>Housewares &amp; Food-Related Items</td>
<td>2,861</td>
<td>0</td>
<td>67</td>
</tr>
<tr>
<td>Cosmetics</td>
<td>4,050</td>
<td>2</td>
<td>203</td>
</tr>
<tr>
<td>Drugs &amp; Biologics</td>
<td>7,506</td>
<td>0</td>
<td>264</td>
</tr>
<tr>
<td>Devices</td>
<td>21,908</td>
<td>0</td>
<td>501</td>
</tr>
<tr>
<td>Radiological Health</td>
<td>682</td>
<td>0</td>
<td>60</td>
</tr>
<tr>
<td>Tobacco Products</td>
<td>547</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Regulatory Authority

• Covered by the Federal Food Drug & Cosmetic Act (section 801)
• Articles are expected to be in compliance at the time of entry
• 801(a): Allows for refusal of imported FDA-regulated products for appearing to be adulterated or misbranded based on evidence
The Import Process

• Importer or designated representative files entry with U.S. Customs and Border Protection (CBP) pending a decision to allow the goods into the U.S.
  
  – Find a Broker by Port:
    https://www.cbp.gov/contact/find-broker-by-port

• If FDA regulated, Customs forwards to FDA

• Human and animal food entries require Prior Notice
Screening

• Review of entries is largely an automated process
• 100% Electronic Screening
• PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting)
Entry Review

• Entry Reviewers: trained Consumer Safety Officers assess entry information
  – Entry data
  – PREDICT results
  – Import Alerts
  – Database review
  – Historical knowledge

• Entry reviewer will decide to:
  – Release the goods
  – Obtain more information
  – Request Detention
Admissibility
FDA Release or May Proceed

• If FDA issues a Release (or “May Proceed”)
  – Product may be distributed
  – FDA still has jurisdiction
    • Import – Standard of evidence is “appearance” of a violation
  – Does not preclude FDA action if a problem is found later
Admissibility
Examination/Sampling

• FDA field personnel are trained in examination and sampling techniques
  – Filth
  – Decomposition
  – Packaging defects
  – Mishandling of products
  – Misbranding (labeling)

• Surveillance sampling across all commodity areas
  – Multiple problem areas
  – Driven by compliance programs, assignments, and increased/targeted surveillance

• Samples analyzed by FDA laboratories
Admissibility
Examination/Sampling, cont.

• If apparent violations are discovered
  – Forwarded to Import Division Compliance Branch for review
  – If supported, compliance officer issues “Notice of FDA Action”
  – Detention and Hearing Process begins

• If no violations are discovered
  – FDA Release
Admissibility
Detention and Hearing Process

• If FDA detains the shipment
  – Importer has the right to submit testimony (provide evidence) to overcome the appearance. “Detention and Hearing Process”
    • Correct the problem
    • Submit a reconditioning proposal (must be approved by FDA)
  – Based on the evidence, the detention will either stand or be overturned
Admissibility: Detention

• “Detention” for FDA is an administrative process
  – Different from a CBP detention
• It is not a physical hold of the product
• Food Drug and Cosmetic Act Section 801(b) allows the owner or consignee to take possession of the articles
  – MUST have a bond in place with CBP
Admissibility: Refusal

• Refusal
  – If the appearance of a violation is not overcome
  – If the product cannot be brought into compliance

• Notice of FDA Action - Refusal of Admission is issued to importer
  – Refused product must be destroyed unless exported
  – Importer’s right to choose within 90 days

• FDA and/or CBP verify refusal activities
• Importer may incur liquidated damages
Import Alerts

• Sufficient evidence to detain goods without examination (Detention Without Physical Examination: DWPE)
• Prevents potential violative products from being distributed into the United States
• Frees up Agency resources to examine other shipments
• Provides uniform coverage across the country
  – Actions & Enforcement page for industry
Import Alerts, cont.

• Firm Alerts vs. Countrywide
• Roughly 212 active Import Alerts
  – Number changes as Import Alerts are created or deactivated
• Criteria for DWPE can be found in FDA’s Regulatory Procedures Manual (RPM) and other publicly available guidance
  – Regulatory Procedures Manual (RPM)
• Firm Alerts vs. Countrywide
Removal from Import Alert

• Firms or importers may petition to be removed from DWPE
  – Industry submits the petition to DIO
  – FDA reviews the petition
  – FDA needs assurance the cause of the violation has been corrected
  – Generally requires evidence of non-violative shipments but depends on the Import alert
    • Documentation demonstrating the product isn’t subject to the Alert

• Import Alerts are publicly available at:
  – http://www.accessdata.fda.gov/cms_ia/ialist.html
Food Facility Registration

• Who Must Register:
  – Domestic or foreign facility engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the U.S
• Food Facility Registration is enforced at the time of Prior Notice submission
• Registration can be accomplished online
  – Registration and Listing
  – Registration Q and A for Industry
FDA Imports Overview

FOOD SAFETY MODERNIZATION ACT (FSMA)
Food Safety Modernization Act (FSMA) Rules

• Foreign Supplier Verification Program (FSVP)
• Voluntary Qualified Importer Program (VQIP)
• Accredited Third-party Certification
• Lab Accreditation Program
• Systems Recognition Program

Foreign Supplier Verification Program (FSVP)

- Requires FSVP importers to develop, maintain and follow an FSVP for each food imported, unless an exemption applies
- Establishes explicit responsibility for importers to ensure the safety of imported food
- Inspections are conducted at the location transmitted by the FSVP importer at entry
April 3, 2020 –

*FDA announced the agency would start remote inspections of FSVP importers.*

In rare situations, such as in response to an outbreak of foodborne illness, FDA may still choose to conduct an onsite FSVP inspection.

In these instances, an FDA investigator will make arrangements to conduct the inspection while practicing the social distancing recommendations provided by the Centers for Disease Control and Prevention.
FSVP Inspections

Outcome: More Effective Oversight of Foreign Suppliers by Importers (FSVP)

1. Number and Percent of FSVP inspections classified NAI, VAI, OAI

The inspection classification is based on the FSVP citations and rankings documented in the Establishment Inspection Report (EIR). FDA classifies inspections in terms of significance of observations and monitors trends at the firm and aggregate level. This information will allow FDA to identify areas of industry in need of outreach and education in coming into compliance with the Foreign Supplier Verification Programs (FSVP) provision.

Note: Current Fiscal Year represents performance year-to-date.

Voluntary Qualified Importer Program (VQIP)

• A voluntary, fee-based program
• Expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains
• Requires third party facility certification for the foreign supplier(s)
• Application portal is open from January 1st – May 31st each year
• **Accredited Third-Party Certification (TPP):** Will perform food safety audits and issue certifications for foreign food facilities and the foods they produce.

• **Lab Accreditation Program:** FDA will establish a program for laboratory accreditation to ensure laboratories meet high-quality standards.

• **Systems Recognition Program:** FDA conducts assessments of other country’s food safety regulatory system to determine if it provides a similar system of food safety protection to that provided by the FDA.

FDA Imports Overview

IMPORT PROGRAM RESOURCES
FDA Data Dashboard

• Provides inspection, compliance and enforcement related data in a graphic format
• Tool allows users to get detailed information and underlying data as well as export graphs

https://datadashboard.fda.gov/ora/index.htm
FDA Data Dashboard, cont.
## Resources

<table>
<thead>
<tr>
<th>Topics</th>
<th>Contact Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE Support Center</td>
<td><a href="mailto:ACE_Support@fda.hhs.gov">ACE_Support@fda.hhs.gov</a></td>
<td>Technical issues related to the FDA Supplemental Guide, required data elements, and general ACE submissions, including entry submissions rejected by FDA. Requests for ACE training/presentations.</td>
</tr>
<tr>
<td>FDA Imports Inquiry</td>
<td><a href="mailto:FDAImportsInquiry@fda.hhs.gov">FDAImportsInquiry@fda.hhs.gov</a> 301-796-0356</td>
<td>General questions regarding FDA import operations and policy, including requests for removal from detention without physical exam.</td>
</tr>
<tr>
<td>Local FDA</td>
<td>FDA Import Offices</td>
<td>First line support for product coding and classification questions, working through the FDA entry admissibility process when the entry has been successfully transmitted to FDA and issues with incorrectly returned firms.</td>
</tr>
<tr>
<td>Division of Food Defense Targeting</td>
<td><a href="mailto:Prior.Notice@fda.hhs.gov">Prior.Notice@fda.hhs.gov</a> 866-521-2297</td>
<td>General questions regarding Prior Notice for food shipments, PN compliance holds and review questions.</td>
</tr>
</tbody>
</table>
## Resources, cont.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Contact Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration of Facilities</td>
<td>Help Desk email: <a href="mailto:FURLS@fda.gov">FURLS@fda.gov</a></td>
<td>Technical issues related to the registration of food facilities and other submissions. Guidance for Industry/Questions and Answers.</td>
</tr>
<tr>
<td></td>
<td>Toll Free: 800-216-7331</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local/International: 240-247-8804</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Guidance for Industry</strong></td>
<td></td>
</tr>
<tr>
<td>Import Program</td>
<td><strong>Import Program</strong> 301-796-0356</td>
<td>General questions regarding FDA import operations and policy including import basics, entry process, actions and enforcements and resources.</td>
</tr>
<tr>
<td>Voluntary Qualified Importer Program (VQIP)</td>
<td><strong>VQIP</strong></td>
<td>Importers can submit their application by submitting a notice of intent to participate by setting up an account via the FDA Industry Systems website.</td>
</tr>
<tr>
<td>FDA.gov</td>
<td><strong>Resources and Information</strong></td>
<td>General questions regarding FDA regulated products, FDA guidance documents, recalls, safety alerts, regulatory information, inspections and compliance and more.</td>
</tr>
</tbody>
</table>
Thank you

Cynthia.ford@fda.hhs.gov