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

International Trade Day
May 17, 2021
FDA Regulations and Current Events

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Objective

- *Provide an overview of FDA jurisdiction and regulations*
- *Communicate FDA's response on critical import operations to protect public health during the COVID-19 pandemic*
- *Share FDA communications and resources*

What We Regulate…

- Human Foods (except for most meat and poultry)
- Drugs (both human and animal)
- Animal Feeds
- Biologics
- Cosmetics
- Medical Devices
- Electronic Products that emit radiation
- Tobacco

Laws Enforced by FDA

- Food Drug & Cosmetic Act
- Bioterrorism Act of 2002
- 1997 Modernization Act
- Fair Packaging & Labeling Act
- Public Health Service Act
- Federal Import Milk Act
- Dietary Supplement Health & Education Act of 1994
- Mammography Quality Standards Act (MQSA)
- Food Safety Modernization Act
- FDA Safety & Innovation Act

Imports Overview

- All imported products are required to meet the same standards as domestic goods.
- Imported products must be pure, wholesome, safe to eat, and produced under sanitary conditions.
- Drugs and devices must be safe and effective (and may require a pre-market application).

Imports Overview

- Cosmetics must be safe and manufactured with approved ingredients.
- Radiation emitting devices must meet established standards.
- All products must have truthful labeling in English.
- Any standardized food must meet the product standard.

Food Drug & Cosmetic Act
Chapter VIII – Imports and Exports

The Federal Food Drug & Cosmetic Act 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

Food Drug & Cosmetic Act
Chapter VIII – Imports and Exports

"**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

Food Drug & Cosmetic Act
Chapter VIII – Imports and Exports

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

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

Food Drug & Cosmetic Act
Chapter VIII – Imports and Exports

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.

Imports Overview

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

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

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

Removal from Import Alert

FDA needs assurance the cause of the violation has been corrected

Firms or importers may petition to be removed from DWPE

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

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FEATURED

FDA Takes Action to Address Coronavirus Disease 2019 (COVID-19)

FDA is working with U.S. Government partners, including CDC, and international partners to address the pandemic.

FDA communication COVID-19 strategies

FDA Informational Resources

Subscribe to receive updated **COVID-19-related information** from the FDA.

FDA communication COVID-19 strategies

CSMS messaging

- #42118616 - Reminder: Update on FDA's Import Operations During The Coronavirus Disease 2019 (COVID-19) Outbreak
- #42253103 - FDA Recommends Use of ITACS During COVID-19 Outbreak

FDA Import Trade Auxiliary Communication System (ITACS)

- ITACS accounts can be requested via the FDA Unified Registration and Listing System (FURLS) at https://www.access.fda.gov/oaa
- Instructions included within the ITACS Account Management Presentation at https://www.fda.gov/industry/import-systems/itacs to request an account.
- ITACS basic functionality can be accessed at https://itacs.fda.gov.

FDA communication COVID-19 strategies

#42590577 - Filing Entries of Hand Sanitizers for FDA

Hand sanitizers are drugs regulated by the FDA and are generally considered as over-the-counter (OTC) drug products.

Hand sanitizer entries should not be disclaim.

Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs

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FDA communication COVID-19 strategies

#42272898- *Information for Filing Personal Protective Equipment and Medical Devices During COVID-19*

- Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA)
- Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

FDA communication COVID-19 strategies

#42272898- Information for Filing Personal Protective Equipment and Medical Devices During COVID-19…continued

- Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.

FDA To Temporarily Conduct Remote Importer Inspections Under FSVP Due to COVID-19

- https://www.fda.gov/food/cfsan-constituent-updates/fda-temporarily-conduct-remote-importer-inspections-under-fsvp-due-covid-19
- Inspection protocol questions may be sent to FDAImportsInquiry@fda.hhs.gov

FDA communication COVID-19 strategies

- Press Announcements

https://www.fda.gov/news-events/fda-newsroom/press-announcements

FDA Resources

- COVID19FDAIMPORTINQUIRIES@fda.hhs.gov

  COVID-19 inquiries associated to the CSMS instructions and product code assistance.

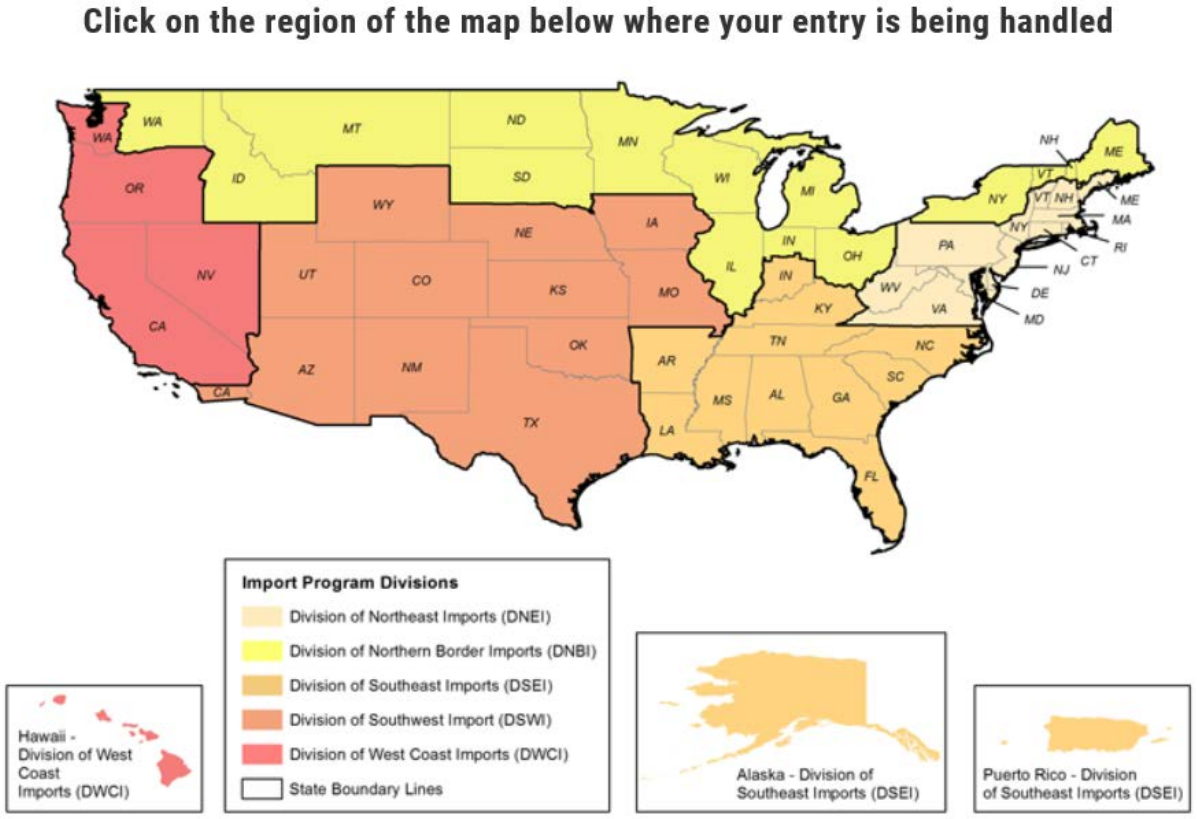
- FDAImportsInquiry@fda.hhs.gov; General Import questions

- DFDT main number 866-521-2297; Prior Notice processing

FDA Resources

"FDA Import Offices and Ports of Entry"

link: https://www.fda.gov/forindustry/importprogram/ucm319216.htm; Specific Import Entry inquiries



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