U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration

Division of Northeast Imports
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What to Consider Before You Import a Human Food

- Thank you for your inquiry regarding Importing Human Foods to the United States. Human food is defined as articles for eating or drinking, including for research use and personal use. For product-specific or regulatory questions, please contact FDA's Center for Food Safety and Applied Nutrition (CFSAN).
- Food imported into the United States must meet the same laws and regulations as food produced in the United States. It must be safe and contain no prohibited ingredients, and all labeling and packaging must be informative and truthful. It is the importer's responsibility to ensure that the imported food is in compliance and to follow the conditions of their customs bond. Please visit the How to Start a Food Business page for a list of requirements.

What to Consider Before You Import a Human Food

1. **Ensure product is compliant with all FDA laws, regulations, and policy/guidance.**

- a. Applicable Regulations: 21 CFR Part 1, 100-169
- b. Applicable Guidance
  - i. Food Guidance & Regulation (by topic)
  - ii. Compliance Policy Guides: Food
  - iii. Compliance Policy Manual Guides: Food
  - iv. Labeling & Nutrition
  - v. Food Good Manufacturing Practices
- c. Labeling Requirements
  - i. Human Food: 21 CFR Part 101
  - ii. Food Labeling Guide
  - iii. Small Business Nutrition Labeling Exemption
- d. Registration Requirements
  - i. Food Facility Registration
  - ii. FSVP Importer Identifier: D-U-N-S number
- e. Other Requirements
  - i. Must submit Prior Notice before goods arrive in the U.S.
  - ii. Foreign Supplier Verification Program

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- **Check FDA's Import Alerts** to determine if your product/manufacturer is subject to Detention without Physical Examination (DWPE) and requirements to secure a release of the shipment.
- **Review FDA's Entry Submission and Review Process.**
- **Consider providing the following information to your Customs broker to transmit to FDA.** Complete and accurate information and documentation will help expedite the review process.
  - Product name(s) and/or descriptions (might be listed on commercial invoice)
  - Intended use of the product(s) in the U.S.
  - Name and address of the physical location of the manufacturer, shipper, importer, and the deliver to party.
    - If any of the entities have an FEI or D-U-N-S number, they may optionally be supplied.
  - A full list of required data elements can be found in the FDA Supplemental Guide by commodity.
    - Please also see: FDA ACE External Outreach Presentation-Human & Animal Food

What to Consider During the Import Process

- At the time of import, the importer will have to provide information about the shipment, related firms, and products to FDA. Once the shipment is transmitted to FDA for review, our systems will conduct an initial evaluation to determine if the product can proceed into commerce or if more information is needed. If more information is needed, the shipment information will be sent electronically to the local FDA office where the goods entered the United States for additional review. The local FDA office may request documents and/or request a physical examination of the products. If a physical examination is performed, FDA will be evaluating the product and labeling for compliance. FDA may collect samples of the products for FDA labs to analyze for known hazards. Depending on the results of the exam and/or sampling, the products will either be proceeded into commerce or held for a compliance review. The local FDA office also makes the final admissibility decision (release or refuse). This page on FDA's Entry Review Process provides additional information.

What to Consider During the Import Process

- **Stay in contact** with your Customs broker and/or FDA and provide requested information in a timely manner.
  - If FDA requests documents or an inspection, provide the requested information and/or documents via ITACS.
    - Documents might include invoices, shipping documents, ingredients list, copies of labels, photos of product, formulations, processing methods, etc.
  - You may provide any information that would help the reviewer determine your product is in compliance with U.S. laws and regulations.

- **Monitor the status** of your entry on ITACS for final admissibility decision.

- **Submit questions** about your shipment to the local FDA office at the port of entry.

Additional Resources

Regulations	Guidance	Labeling	Registration	Other	Systems Information
21 CFR Part 1, 100-169	Guidance & Regulation (by topic)	Food Labeling Guide	Food Facility Registration	Prior Notice	FDA Supplemental Guide for ACE
Color Additives: 21 CFR Part 70-82	Compliance Policy Guides: Food		Food Facility Registration Step-by-Step Guide	PNSI Step-by-Step Guide	Product Code Builder
Food Additives: 21 Part 170-189	Compliance Policy Manual Guides		FSVP Importer Identifier: D-U-N-S number	Prior Notice Q & A	Product Code Builder Tutorial
	Labeling & Nutrition			Foreign Supplier Verification Program	
	Food Good Manufacturing Practices			FSVP Q & A	
				Import Alerts	

ACE Transmission Requirements: Human Foods

- A full list of data elements can be found in the FDA Supplemental Guide.

- Program Code: FOO
- Processing Code: PRO (processed food) or NSF (natural state food) or ADD (food or color additive)
- Intended Use Code: See the FDA Supplemental Guide for ACE
- Affirmations of Compliance: See the FDA Supplemental Guide for ACE

- Please also see: FDA ACE External Outreach Presentation-Human and Animal Food