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SOLUTIONS FOR
SMARTER LOGISTICS

IBC GUIDE FOR IMPORTING PRODUCTS SUBJECT TO FDA/USDA REQUIREMENTS

OCTOBER 2025

In the United States, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) divide the responsibility for regulating imported life sciences commodities based primarily on the type of product. The FDA oversees most food products, drugs, and cosmetics, while the USDA is primarily responsible for meat, poultry, and egg products.

The following instructions are provided as a guide to what the shipper is required to do for shipments of these commodities. In some instances, this is related to registration that must be carried out prior to shipping, in addition to what is required to be declared on air waybills and commercial invoices.

There is a requirement for certain imports to have an original, clear, and concise statement on the producer's or shipper's letterhead for USDA inspectors. This document must accompany the shipment and declare specific information, such as the material's contents and origin, to prevent delays and ensure compliance with import regulations.

Key requirements

- **Original statement:** An original, signed statement is necessary, not a copy.
- **Producer/shipper letterhead:** The document must be printed on the official letterhead of the producer or shipper.
- **Clear and concise:** The information and description must be easy for inspectors to read and understand.
- **Availability for review:** The statement must be available at the port of arrival for the USDA inspector's review.
- **Required content:** The specific content depends on the product but typically includes:
- An identification of the material.
- A declaration that it doesn't contain other animal-derived material (e.g., from livestock or poultry).
- A declaration that the material was not derived from animals inoculated with or exposed to infectious agents of agricultural concern.
- For certain products, a declaration that the material is produced by microbial fermentation, or that it will be used only in vitro.

USDA inspections may be required and may delay clearance if the importer has not obtained a license or permit prior to shipment. For various types of content, there are USDA guidelines that will assist you in completing the required declaration.

BIOLOGICAL PRODUCTS

USDA-regulated imports

The USDA's regulation of imports, primarily through its Animal and Plant Health Inspection Service (APHIS) and Food Safety and Inspection Service (FSIS), focuses on protecting U.S. agriculture from pests and diseases.

Product categories:

- **Meat and poultry:** The FSIS inspects imported meat, poultry, and certain processed egg products to ensure they are safe and properly labeled.
- **Live plants and plant products:** APHIS regulates the importation of live plants, seeds, fruits, vegetables, cut flowers, and wood products to prevent the introduction of foreign plant pests.

- **Animals and animal products:** The USDA restricts the entry of certain animals and animal products to prevent the spread of animal diseases.
- **Genetically engineered organisms (GEOs):** The USDA, through APHIS, regulates the importation and movement of GEOs, including plants.
- **Soil :** Soil is regulated because it can contain pests and contaminants.

Further information regarding the regulations for a particular commodity may be found at:

www.usda.gov/wps/portal/usdahome

- **Placement of documents:** The letterhead statement should be included with shipping documents like the invoice or manifest, but not inside the shipping containers.

Consequences of non-compliance

- Failure to provide the correct information can result in delays to the shipment.
- If the material cannot meet the criteria without the proper declarations, a USDA import permit may be required.

Biological Samples

Biological specimens and samples used for non-clinical research use do not fall under the purview of FDA. If the biological specimens being imported are intended for use **ONLY** for testing in a clinical laboratory or for basic scientific research and are not articles intended for the prevention, treatment, diagnosis, or cure of diseases or conditions in human beings, then the specimens are not considered to be biological products subject to licensure by FDA, nor would they appear to be a drug or device. As such, biological specimens for testing in a clinical laboratory or for basic scientific research do not require FDA review and should be disclaimed. FDA recommends that importers clearly indicate the shipment contents and intended use on any associated documentation/labeling. However, other federal agencies may have requirements that apply to biological specimens. Importers should confirm with the Center for Disease Control and Prevention (CDC) as well as Animal and Plant Health Inspection Service (APHIS) whether permits are required.

· CDC: https://www.cdc.gov/import-permit-program/php/ or email importpermit@cdc.gov.

· APHIS: https://www.aphis.usda.gov/animal-product-import

Biological specimens intended to be used for processing or manufacturing HCT/Ps or biological products, drugs, or devices, are subject to FDA jurisdiction and must meet FDA's requirements for HCT/Ps, biological products, drugs, and/or devices.

For more information on biological specimens, the following website is very helpful: Importing CBER-Regulated Products: Clinical Laboratories and Basic Scientific Research | FDA

COSMETIC PRODUCTS & SKIN CARE

All skin care and cosmetic products are subject to import inspection and approval from the FDA. Specific information including a full list of ingredients for each product should be included with the Customs paperwork. Cosmetics must be produced under sanitary conditions, be safe and be made from approved ingredients.

FDA-regulated imports

The FDA regulates a broad range of products to ensure public health and safety. Imported FDA-regulated products must meet the same standards as domestically produced goods.

Product categories:

- **Human and animal foods (most kinds):** This includes dietary supplements, seafood, fruit, vegetables, and food and color additives. The FDA regulates all food products except for most meat, poultry, and some egg products.
- **Human and veterinary drugs:** The FDA regulates active pharmaceutical ingredients, prescription and over-the-counter medications, and veterinary medicines and devices.
- **Medical devices:** Regulated devices include surgical instruments, bandages, contact lenses, and pacemakers.
- **Cosmetics:** Products such as shampoo, makeup, creams, and perfume fall under FDA regulation and may be subject to MoCRA registration.

  https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra
- **Radiation-emitting electronic products:** This includes items like X-ray machines, microwave ovens, and laser pointers.
- **Tobacco products:** The FDA regulates cigarettes, smokeless tobacco, e-cigarettes, and other tobacco items.

FDA Approval and Inspection

- **No pre-market approval (except color additives):** The FDA does not approve most cosmetic products or ingredients before they are marketed in the U.S.
- **Color additives are an exception:** Any color additives used in cosmetics must be approved by the FDA for their intended use, and some may require pre-certification.
- **Import inspection:** Upon arrival, FDA personnel will inspect the products to ensure they are compliant with U.S. regulations.
- **Legal responsibility:** The importer and/or manufacturer is legally responsible for ensuring products are safe and properly labeled.

Import and customs requirements

- **Customs paperwork:** You must include all necessary information with your customs paperwork, including a full list of ingredients for each product.
- **Safety and labeling:** Products must be safe for consumers and properly labeled.
- **Adulterated and misbranded products:** Products cannot be adulterated (e.g., made under unsanitary conditions) or misbranded.
- **Harmonized Tariff Schedule (HTS):** Products are classified under the HTS, and the correct classification will determine duties and tariffs.

Important considerations

- **Drugs vs. cosmetics:** Some personal care products may be classified as drugs, which have different and stricter requirements for importation.
- **Registration and listing:** Recent legislation has introduced new requirements, including registration of cosmetic products, depending on the product's category and intended use.

Cosmetic and Skincare Products

Regulated by the Food and Drug Administration
www.fda.gov

Cosmetics must be manufactured under sanitary conditions, be safe for use, and contain only approved ingredients.

Required Invoice Information for Each Product

For **each individual product**, the following details must be clearly listed on the Commercial Invoice:

- **Type of Product** (e.g., skin lotion, pancake makeup)
- **Quantity and Type of Container** (e.g., plastic or glass; tube or bottle)
- **Country of Manufacture** *(must be listed separately for each product from a different manufacturer)*
- **Itemized Value** of the product
- **Complete List of Ingredients**
- **FDA Product Code**
- **Full Name and Address of the Manufacturer**

The FDA product code can be found at:
www.accessdata.fda.gov/scripts/ora/pcb/index.cfm

PHARMACEUTICALS

The importation of drugs that lack FDA approval, including foreign versions of FDA-approved drugs, is illegal under the U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) because it violates the prohibition against the interstate shipment of unapproved new drugs. The law places the burden on the importer to prove that the drug they are trying to bring into the country is indeed FDA-approved.

Key points

- **General prohibition:** The FD&C Act bans the interstate shipment, including importation, of any new drug that has not been approved by the FDA.
- **"Unapproved new drugs":** This category includes drugs that have not been manufactured in accordance with or pursuant to an FDA approval, even if they are foreign-made versions of drugs approved in the United States.
- **Enforcement:** The FDA can refuse the admission of any drug that appears to be unapproved, misbranded, or adulterated.
- **Burden of proof:** The importer is responsible for proving that the drug they are attempting to import is following the law.
- **Personal use:** The prohibition on unapproved drug imports applies to personal use as well as commercial use.

According to the U.S. Federal Food, Drug, and Cosmetic Act, the burden of proof is on the importer to demonstrate that a drug is approved by the Food and Drug Administration (FDA). When FDA officials refuse the importation of a drug that "appears" to be unapproved, it is the importer who is responsible for providing evidence that the drug complies with all U.S. requirements.

Steps for proving FDA approval

To prove a drug is approved for importation, the importer must provide accurate and complete documentation that meets FDA standards. The process for clearing an imported drug includes the following steps:

1. **Entry submission**: Information on the imported drug is submitted to U.S. Customs and Border Protection (CBP). This data is then transmitted to the FDA for review.

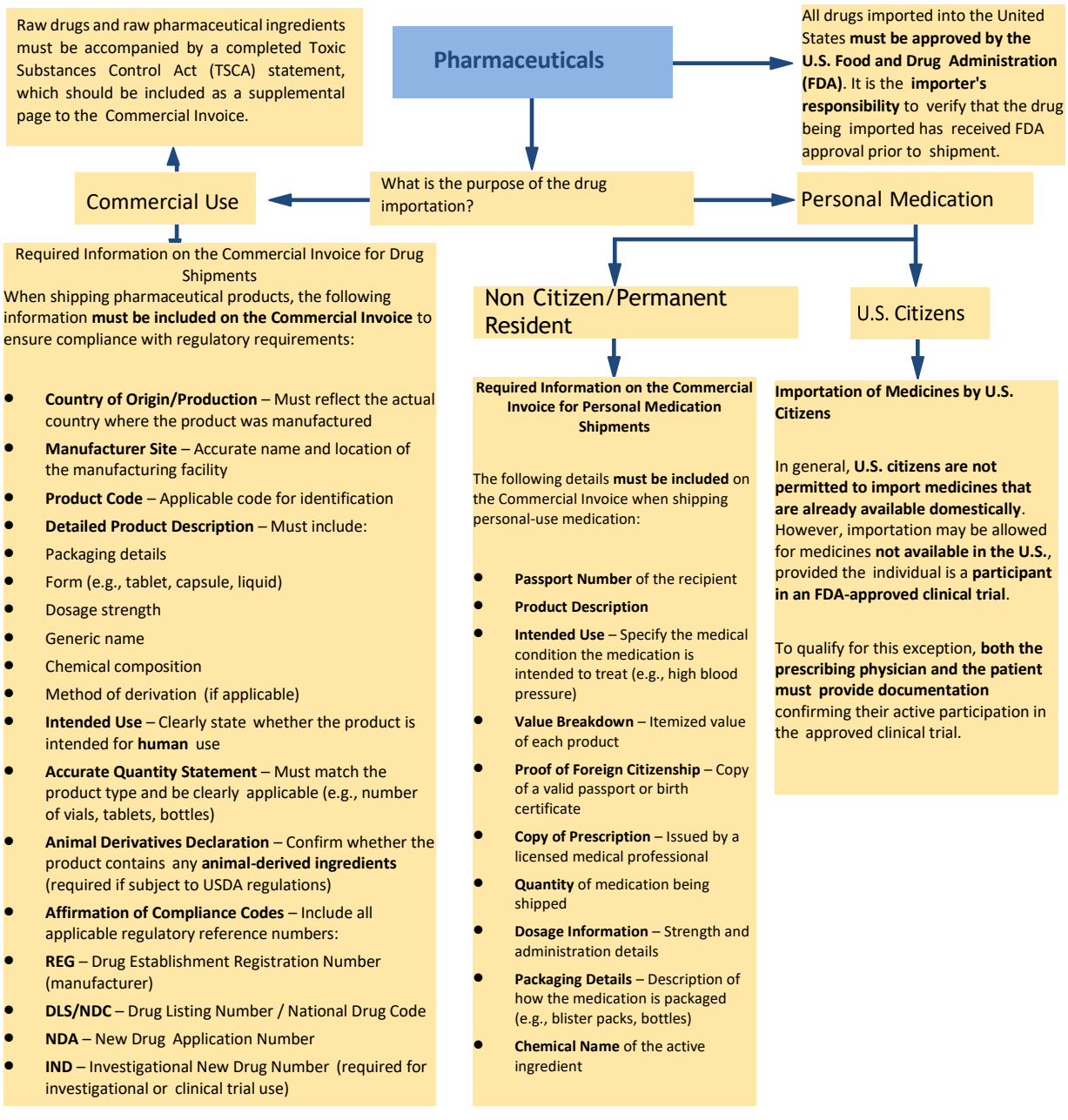
2. **Affirmations of Compliance (A of C)**: The importer or their customs broker should submit correct Affirmation of Compliance codes to certify the product meets certain standards. For drugs, this can include but not limited to providing the drug registration number (REG), drug listing number (DLS), and drug application number (DA).

3. **Registration and listing verification**: The FDA will verify that the manufacturer is registered, and the product is listed in the FDA's internal databases. The information declared must match the agency's records.

4. **Drug application verification**: If a drug requires a new drug application (NDA), abbreviated new drug application (ANDA), or other authorization, the FDA will verify the declared application number against its data. Inaccurate or missing information can cause delays or detention.

5. **Admissibility determination**: If all information is correct and matches FDA systems, the product may be electronically released into U.S. commerce. However, the FDA may manually review high-risk products or those with inaccurate information. In such cases, the agency can request more documents or conduct a physical examination and sample collection to confirm compliance.

6. **Resolution of detention**: If the drug is detained because it appears to violate the act, the importer has an opportunity to provide testimony or other evidence to prove its admissibility. If a product is refused admission, it must be re-exported or destroyed under supervision.



MEDICAL DEVICES

Foreign firms must meet all applicable U.S. regulations, including FDA requirements, to import medical devices or radiation-emitting products into the U.S. because the FDA does not recognize foreign regulatory approvals. This involves complying with U.S. rules before, during, and after importation, which includes establishment registration, device listing, and ensuring products meet safety and performance standards.

Before importing

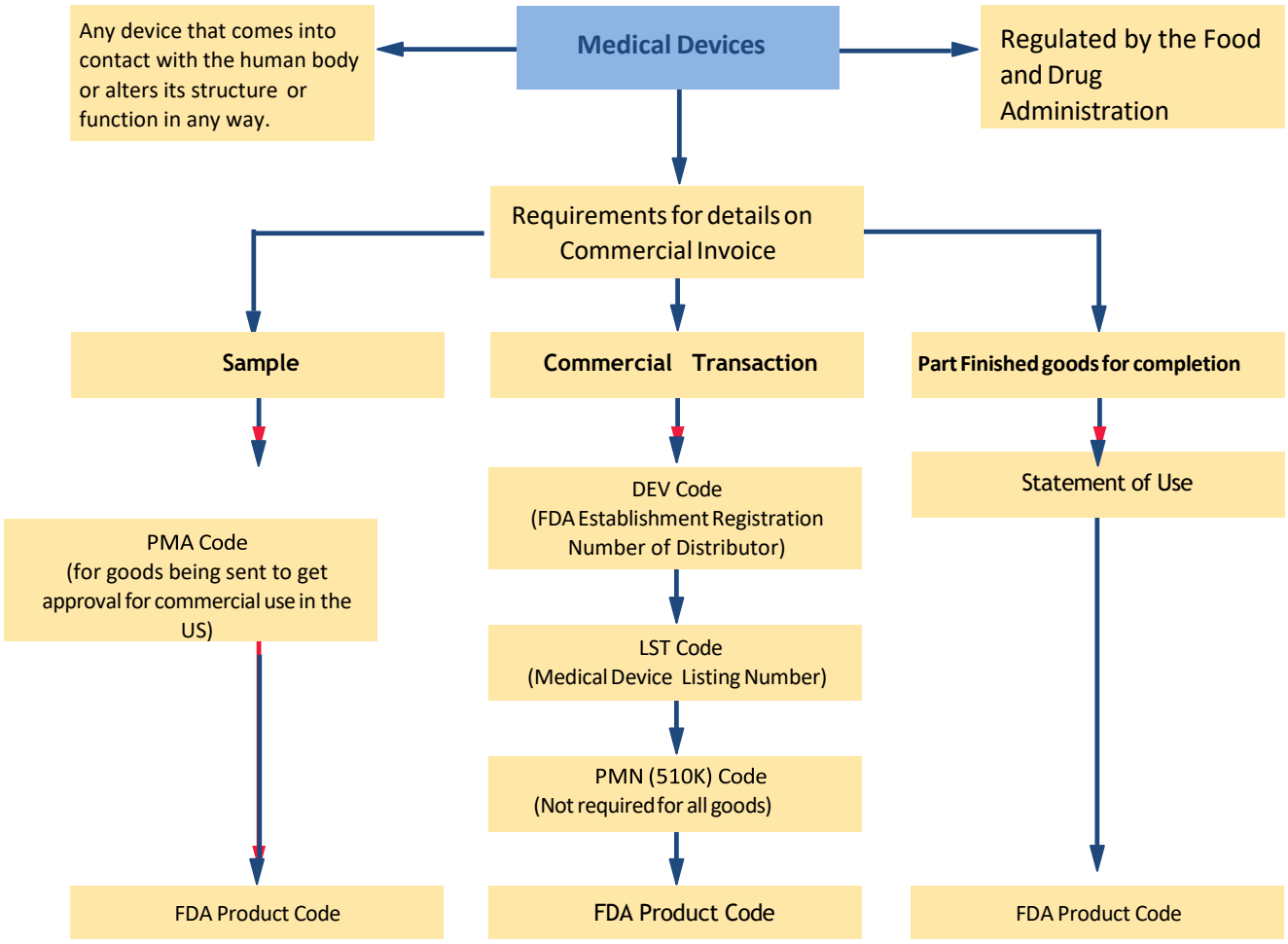
- **Appoint a U.S. agent:** Foreign manufacturers must designate a U.S. agent to act as a liaison with the FDA. This agent must reside or have a place of business in the U.S.
- **Establishment registration and device listing:** The foreign manufacturer must register its establishment with the FDA annually and list all devices intended for commercial distribution in the U.S. The U.S. importer must also register their establishment.
- **Obtain premarket authorization:** Depending on the device's risk classification (Class I, II, or III), the manufacturer must gain premarket clearance or approval from the FDA.
    - **Class I (low risk):** Many Class I devices are exempt from premarket review but still need to be registered and listed.
    - **Class II (moderate risk):** Most Class II devices require a Premarket Notification (510(k)) submission to demonstrate that they are substantially equivalent to a device already on the market.
    - **Class III (high-risk):** These devices require a rigorous Premarket Approval (PMA) submission based on scientific evidence to prove safety and effectiveness.
- **Implement Quality System Regulation (QSR):** Foreign manufacturers must comply with the FDA's Quality System Regulation (21 CFR Part 820), also known as Current Good Manufacturing Practices (CGMP). The FDA may inspect foreign manufacturing facilities to ensure compliance.
- **Ensure proper labeling:** All devices must be labeled in accordance with FDA regulations, including a Unique Device Identification (UDI).
- **For radiation-emitting products:** Foreign manufacturers must submit a radiation safety product report and meet other radiation safety requirements.

During importation

- **Provide import documentation:** All necessary documents, such as the commercial invoice, manufacturer's FDA registration, device listing number, and premarket approval number, must be provided to U.S. Customs and Border Protection (CBP) through the Automated Commercial Environment (ACE) system.
- **Submit Form FDA 2877 for radiation-emitting products:** For radiation-emitting products subject to a performance standard, importers must submit Form FDA-2877, "Declaration of Products Subject to Radiation Control Standards," at the time of entry.
- **Pass inspection:** CBP refers all FDA-regulated products for review, and the FDA may conduct inspections and analyze samples to verify compliance.
- **Respond to detention:** If a product is detained, the importer can provide evidence of compliance or propose a plan to bring the product into compliance. If compliance cannot be proven, the product may be refused entry and must be destroyed or re-exported.

After importation

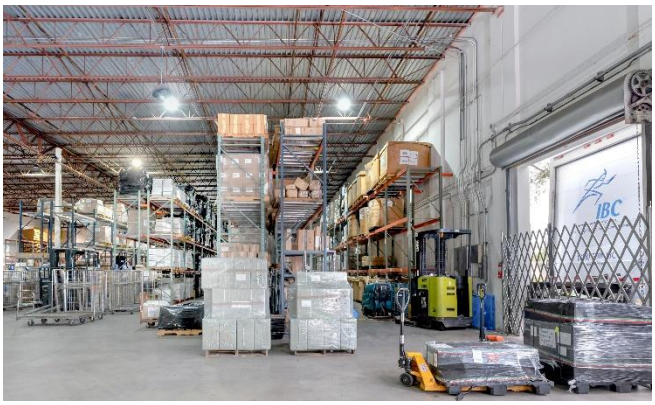
- **Medical Device Reporting (MDR):** Both manufacturers and initial importers must report certain device-related adverse events, such as deaths, serious injuries, and specific malfunctions, to the FDA.
- **Maintain event files:** Importers must keep an event file for every adverse event and forward all product complaints to the manufacturer.
- **Track certain devices:** For specific devices, manufacturers and importers must comply with the Medical Device Tracking regulation to track devices through the distribution chain.
- **Post market surveillance:** The FDA may require post market surveillance studies for certain devices, including those with premarket approval.
- **Reports of corrections and removals:** Initial importers are required to submit reports of corrections and removals to the FDA.



All FDA guidelines and advice on product and listing codes can be viewed at the FDA website **http://www.fda.gov**

CHEMICAL MATERIALS

U.S. government agencies require that the invoice include a declaration specifying the exact chemical materials contained in the shipment.



Chemicals

Regulated by the U.S. Department of Agriculture

This information must be provided as **original statements on the producer's or shipper's official letterhead**, presented clearly and concisely, and made available for review by agriculture inspectors at the port of arrival.

Required Information on the Commercial Invoice

The following details **must be included** on the Commercial Invoice:

- Source of derivation (e.g., plant, synthetic, recombinant)
- Method of synthesis (chemical or recombinant)
- Statement confirming **"Contains no animal derivatives"**
- Proper chemical name, form, and intended use
- Declaration of **"Non-infectious / Non-contagious"** (if applicable)
- Reason for importation
- List of ingredients (if applicable), along with trade and generic names

To help prevent potential delays, please include the following statement on both the **Commercial Invoice** and in the **description field of the Air Waybill**:

"Not Restricted per IATA DGR"

It is also recommended to attach the **Material Safety Data Sheet (MSDS)** to the Commercial Invoice for reference.

In addition, a **Toxic Substances Control Act (TSCA) statement** must be completed and included as a **supplemental page** to the Commercial Invoice.

Further information

Additional details can be found at **www.usda.gov**

FOOD AND DRUG ADMINISTRATION

Food and Drink

Regulated by the Food and Drug Administration **www.fda.gov**

Prior Notice is required for all shipments containing food that are made in a commercial establishment.

Customers outside the U.S. need to set up an Account for Prior Notices before shipping:
http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ ucm2006836.htm

FDA Technical Support: **1 800 216 7331**

Sending Gifts?
These must be labeled as **"Gift "** If the gift is sent from a **retail establishment** and contains **food or beverages**, **Prior Notice** is required.

- The Prior Notice Number is required on ALL shipments going to the U.S.
- containing food and drink
- The number should be visible in the description box of the Air Waybill
- The description should read "Food/Beverage Product"
- A printed copy of the Prior Notice should also be attached to the
- Commercial Invoice to which a complete list of all commodities are
- broke down. This takes away the requirement on the Commercial
- Invoice.

Requirements for Shipping Alcohol to the U.S.

- The **consignee** in the U.S. must hold a valid **Federal Alcohol Permit**.
- The **importer** must obtain either a **Certificate of Label Approval (COLA)** using **TTB Form S100.31** or a **COLA Waiver prior to importation**.
- The importer must also possess all **applicable state-level permits**.
- Shipments must be sent only to **approved destination states**: **CA, CT, FL, GA, IL, MO, NC, NY, OR, PA, TX, WA, KY, PR**
- The **Importer Permit Number** must be clearly stated on the **Commercial Invoice**.
- A valid **Prior Notice Number** is required.
- A **Power of Attorney (POA)** must be on file with the importer.

Exceptions

Personal Food Shipments Exemption
This exemption applies to **non-commercial food shipments** sent **from one individual to another**, such as **gifts personally purchased and shipped by the sender outside the U.S.**

FDA REGULATED "FOOD" IMPORTS

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (commonly known as the Bioterrorism Act of 2002 or BTA) includes provisions aimed at safeguarding the United States from bioterrorist threats, particularly those targeting the nation's food supply. A significant focus of the Act is on food imported from foreign sources. In response, the U.S. Food and Drug Administration (FDA) issued regulations establishing specific requirements for the importation of food and food products.

These regulations include two key requirements:

1. **Facility Registration**
2. **Prior Notice of Imported Food Shipments**

1. Facility Registration

The FDA requires both domestic and foreign facilities that manufacture, process, pack, or store food for human or animal consumption in the U.S. to register with the agency. However, certain types of facilities are exempt from this requirement, including:

- Farms
- Retail food establishments
- Restaurants
- Non-profit food operations that prepare or serve food directly to consumers

Note: Private individuals who send or receive food items for personal use (e.g., holiday gifts) are not required to register their facilities.

2. Prior Notice of Imported Food Shipments

Under the Bioterrorism Act of 2002, the FDA requires that U.S. purchasers, importers, or their agents submit **Prior Notice (PN)** to the FDA before food intended for human or animal consumption is imported or offered for import into the United States. This requirement allows the FDA to evaluate the shipment and determine whether inspection is necessary.

- Prior Notice must be submitted **no less than four hours** before the arrival of the flight (or other mode of transport)
- It may be submitted **no more than five days** in advance of the anticipated arrival
- PN must be submitted for the **first port of arrival** in the U.S.

What Is Considered "Food"?

The term *food* includes items consumed by humans or animals, including components and ingredients. Examples include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic drinks and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities intended for use as food or food components
- Canned and frozen foods
- Baked goods, snacks, and candy (including chewing gum)
- Live food animals
- Animal feed and pet food

Prior Notice Requirements Apply Regardless of:

- **Quantity** – Applies to full shipments, samples, or small amounts
- **Purpose** – Applies to goods intended for consumption, testing, research, etc.
- **Type of transaction** – Applies to commercial sales, samples, gifts, and donations

Exemptions from Prior Notice:

- **Personal food shipments** – Food sent person-to-person for non-commercial purposes (CBP MAY APPLY DISCRETION)

- **Food included in household goods** – Includes shipments for military, civilian, government agency, or diplomatic relocations

Timing Requirements:

Additional Prior Notice Exemptions

The following types of food shipments are **exempt** from FDA Prior Notice requirements:

- **Food purchased by a traveler and mailed or shipped** to their own U.S. address
- **Gifts purchased at a commercial establishment** and shipped by the purchaser (not the seller) (CBP MAY APPLY DISCRETION)
- **Food contained in diplomatic pouches**

Important Note: These exemptions do *not* apply to shipments sent from retailers or distributors to individuals (e.g., gift baskets). Such shipments **do require** Prior Notice.

USDA-Regulated Products

Food products regulated exclusively by the **U.S. Department of Agriculture (USDA)**—including **meat, poultry, and certain egg products**—are **not subject** to FDA Prior Notice, provided they fully comply with USDA regulations.

FDA Prior Notice Procedures (via IBC Couriers, Inc.)

1. When Prior Notice is Filed by the Shipper

If the shipper files the Prior Notice, IBC **requires a copy of the Prior Notice Confirmation** for each food item. This may be submitted as a:

- **PN Confirmation Detail Sheet**, which includes:
  - Product description
  - Product code

Important:

- Confirmation number(s) must be clearly listed on the **shipping invoice**
- The **air waybill** must clearly describe the contents as **Food** or **Food Product**
  (See: FDA Prior Notice 2004 Update)

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2. When IBC Files Prior Notice on Behalf of the Shipper

If IBC submits the Prior Notice on your behalf, the **following information must be included on the shipping invoice** (see IBC *FDA Required Information for Prior Notice Submission*):

Each food item must be identified separately, with the following details:

- Common, usual, or market name of the product
- Quantity (from smallest unit to largest container), including type of packaging
- Lot or code numbers or other unique identifiers
- Full name and address of the **manufacturer or supplier**, including **FDA registration number** (if available)
- **Country of origin** of the product
- Full name and address of the **shipper**, including **FDA registration number** (if available)
- Full name and address of the **importer, purchaser, or final consignee**, including **FDA registration number** (if available)
- Clear identification of the item as **Food** or **Food Product** on:
- The IBC pre-alert air waybill
- The invoice description

Note: IBC will only submit Prior Notice on your behalf if IBC Customs Brokerage, Inc. is acting as the **Customs broker** for your shipment.