# MASTER CUSTOMS SPECIALIST (MCS) COURSE

## Part 5: Admissibility Requirements | Module 15: Food and Drug Administration (FDA)

**List of Lessons:**



## INTRODUCTION

In addition to CBP, imports are governed by many other government agencies often called Partner Government Agencies (PGAs).

Each agency has its own area of authority and its own title within the Code of Federal Regulations. The Food and Drug Administration (FDA) can be found in Title 21 (or 21 CFR).

The FDA is tasked with a number of roles that broadly fall under two umbrellas – protecting consumers and the food supply.

Examples of products regulated under the FDA include:

- Food
  - The U.S. Department of Agriculture (USDA) takes the lead in regulating certain aspects of meat, poultry and eggs.
- Drugs
- Biologics
- Medical Devices
- Radiation-Emitting Products (specifically electronic products)
- Cosmetics
- Veterinary Products
- Tobacco

## Lesson 1: Importation of Food

Food is defined in Section 201(f) of the Food, Drug & Cosmetics Act (FD&C Act) [21 USC 321(F)] as:

- Articles used for food or drink for man or other animals;
- Chewing Gum; and
- Articles used for components of any such article.

***Food Examples***

- Infant formulas
- Food additives
- Dietary supplements
- Bottled Water

**Bioterrorism Act Overview**

As a response to the terrorist attacks of September 2001, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA) (P.L. 107-108-June 12, 2002) to provide new authority to protect the U.S. food supply against terrorist attacks and threats.

- Three key changes resulting from the BTA are:
    - CBP personnel at many U.S. ports of entry have been formally commissioned and specially trained to conduct BTA cargo and other examinations under the BTA. CBP personnel have the authority to hold suspect shipments for further examination and sampling.
    - Registration of food facilities is required under Title III of the BTA, which amended the FD&C Act.
    - Prior Notice of imported food shipments is required under Title III of the BTA, which amended the FD&C Act.

**Food Facility Registration – When Required**

The regulations applicable to registration of food facilities are found in 21 CFR Part 1, Subpart H. The purpose of registration is to determine the location of a potential bioterrorism incident or outbreak of illness, and to notify the facilities involved.

Registration is required of facilities that manufacturer, process, pack, or store food (§ 1.226). A foreign facility does not need to register if food from that facility is sent to another facility outside the United States for further processing or manufacturing. However, if the second facility performs only a minimal function such as labeling packages, both facilities must register.

**Food Facility Registration – Exclusions**

The following classes of facilities are *not* required to register:

- Farms
- Retail food establishments
- Restaurants
- Nonprofit food establishments
- Fishing vessels
- Facilities handling only meat, poultry, or egg products that are regulated by the USDA.

**Food Facility Registration – Designated U.S. Agent**

Foreign food facilities must designate an Agent who resides or maintains a place of business in the United States [§1.227(b)(13)].

- The agent serves as a communications link between the FDA and the foreign facility. FDA will contact the agent in case of an emergency unless a different emergency contact is specified in the registration.
- Representations of the agent will be considered as those of the facility.
- Providing documents to the agent is considered to be equivalent to providing them to the foreign facility.

**Food Facility Registration - Submission**

Registration is free.

- Electronic registration can be done on the FURLS system (http://www.fda.gov/furls). FDA strongly encourages electronic registration. Facilities that register electronically are considered to be registered as soon as FDA transmits their confirmation number.
- For those who do not have reasonable access to the internet, registration can be done by mail or fax. Facilities that register by mail or fax will be not be considered registered until the FDA enters their information into the registration system and the system generates a registration number.

**Food Facilities Registration - Data Required**

The required information for registration includes the names, addresses, and phone numbers of the following parties (§ 1.232):

- Facility;
- Parent company;
- Owner or operator in charge of the facility;
- U.S. agent of a foreign facility.

Facilities must provide an emergency contact phone number. Foreign facilities that do not designate an emergency contact must provide an emergency contact phone number of their U.S. Agent.

**Food Facility Registration - Updates and Cancellations**

- Registration must be **updated within 60 days** when any of the required information changes.
- Registration must be **cancelled within 60 days** when the ownership of a facility changes. The new owner must then register the facility with its information.
- Registration must be cancelled when a facility ceases operations or ceases to provide food for consumption in the United States.

Updates and cancellations can be transmitted electronically. Registration will be considered updated when FDA transmits confirmation. They may also be submitted by mail or fax for those who do not have reasonable access to the Internet.

**Food Facility Registration - Not Complete at Time of Import**

Shipments offered for import from a foreign facility that has not registered are subject to being held (§ 1.285).

- To resolve the hold, the foreign facility can register and obtain a registration number.
- The importer can request an FDA review as to whether the facility is subject to the registration requirement.

**Prior Notice - Exclusions**

- Prior notice is not required for meat, eggs, and poultry, which are subject to the exclusive jurisdiction of the USDA.
- Non-commercial importations of food by individuals are not subject to the prior-notice requirement. Examples of non-commercial importations include food that is made by an individual in their residence and sent as a personal gift and food for use by an individual when it is carried by that individual when arriving in the United States.

**Prior Notice – Submission Timelines**

The minimum number of hours prior to arrival that prior-notice must be submitted depends upon the mode of transportation:

  - Water – 8 hours prior to arrival;
  - Air– 4 hours prior to arrival;
  - Rail – 4 hours prior to arrival;
  - Truck – 2 hours prior to arrival;
  - International Mail – before the food is sent to the United States

- Prior Notice must be submitted either through ACE or through the FDA Prior Notice System Interface (PNSI).
- Prior Notice may not be submitted more than 30 days prior to the anticipated date of arrival if submitted via ABI

- Prior Notice may not be submitted more than 15 days prior to the anticipated date of arrival if submitted via PNSI.

FDA will confirm receipt of a submission with a reply message containing a prior notice confirmation number.

**Prior Notice – Data Requirements**

The information that must be provided in a prior notice is specified in § 1.281(a)(1) through (a)(17). The following is an overview of the required information:

- Submitter
- Identity of transmitter if different from submitter
- Entry type and entry number
- Identification of food product
- Manufacturer or grower (including registration number)
- FDA Country of Production
- Identity of shipper if different from the manufacturer
- Country from which product was shipped
- Anticipated arrival information
- Name and full address of importer
- Name and full address of owner if different from importer or ultimate consignee
- Name and full address of ultimate consignee
- Mode of transportation and carrier information
- Shipment information, such as bill of lading number and voyage or flight number

**Prior Notice – Country of Production**

The FDA Country of Production as defined in § 1.276(a)(4) is not always the same as the country of origin as defined in the CBP Rules of Origin in 19 CFR Part 102.

The FDA origin is the country where the article was made, whereas the CBP country of origin could be determined by a production process that results in a tariff shift.

**Prior Notice – Imports without PN filing**

Food that arrives at a port of entry without prior notice, or with prior notice that is reviewed and found to be inaccurate, will be refused admission and held at the port (§ 1.283). The following actions can be taken by the importer:

- Export the article under supervision of CBP
- Submit or resubmit prior notice
- Request review by FDA whether prior notice is required for the article or whether the prior notice that had been filed is accurate

## Food Safety Modernization Act (FSMA) of 2011 Overview

Each year foodborne diseases present a significant public health burden. About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die, according to recent data from the Centers for Disease Control and Prevention. This is largely preventable.

The FSMA shifted the focus of enforcement from reaction to prevention of food safety problems. Key provisions of the FSMA include:

- Operators of food facilities are required to evaluate hazards and implement preventive controls.
- FDA is mandated to target inspection resources according to known safety risks.
- FDA has the authority to mandate recalls.

## FSMA – Foreign Supplier Verification Program (FSVP) - Overview

The FSMA established the **Foreign Supplier Verification Program** (FSVP). It is listed in Section 301 of the FSMA and under 21 CFR Subpart L.

- FSVP applies to all food imported or offered for import into the United States, unless exempted. Exempted items are:
    - Certain juice, fish, and fishery products which are already subject to verification under FDA's HACCP regulations;
    - Food for personal consumption;
    - Food that is transshipped or imported for export;
    - Alcoholic beverages;
    - Food for research and evaluation;
    - Meat, poultry, or eggs, that at the time of importation are subject to the requirements of the U.S. Department of Agriculture.

- The program requires importers to perform risk-based foreign supplier verification activities to verify that imported food is produced in compliance with the requirements of hazard analysis and risk-based preventive controls of section 418 of the FD&C Act (21 U.S.C. 350g) or the produce safety standards of section 419 of the FD&C Act (21 U.S.C. 350h).
- Preventive controls must be implemented to significantly minimize or prevent the occurrence of such hazards.
- Assurances must be provided that food is not adulterated or misbranded.

## FSMA – FSVP - Program Design

For each food that is imported, the importer must develop, maintain, and follow an FSVP (§ 1.502). Prior to importing a food, the FSVP importer must determine and document which verification activities are necessary to provide assurance that hazards have been significantly minimized or prevented [§ 1.506 (d)].

Supplier verification activities include:

- Onsite audits;
- Sampling and testing of a food;
- Review of the foreign supplier's food safety records;
- Review of other supplier verification activities that are appropriate based on foreign supplier performance and the risks associated with the food.

**FSMA – FSVP – Hazard Analysis**

A hazard analysis of each food must be performed to determine whether there are any hazards requiring a control (§ 1.504). The hazard analysis must be written, regardless of its results.

- The analysis must include the following types of hazards:
  - Biological, including parasites and pathogens
  - Chemical, including radiological, pesticide residues, and unapproved food or color additives
  - Physical hazards, such as glass or metal fragments

**FSMA – FSVP - Evaluation**

The FSVP importer must evaluate and document the foreign supplier's performance with respect to the hazards identified in the hazard analysis (§ 1.505). The evaluation must include the following:

- The foreign supplier's procedures, processes, and practices related to the safety of the food
- FDA compliance history, such as FDA warning letters or import alerts
- Other safety history, including results from tests and audits relating to the safety of the food

**FSMA – FSVP – Qualified Individual**

The FSVP hazard analysis and evaluation must be conducted by a qualified individual (§ 1.503).

- A qualified individual must have the education, training, or experience necessary to perform their assigned activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.
- The FSVP importer may use the results of a hazard analysis and evaluation that was performed by a qualified individual of another entity.
  - The importer's review and assessment of the hazard analysis and evaluation must be documented.

**FSMA – FSVP – Food controlled after import**

When importing a food for which hazards are controlled after importation by the importer's customer, it is not necessary to conduct foreign supplier verification activities (§ 1.507).

- The importer must disclose in documentation that accompanies the food that the food is not processed to control for the identified hazards.
- Written assurance must be obtained from the customer that they are following procedures to significantly minimize or control the identified hazards.

**FSMA – FSVP - Modifications**

FSVP requirements are modified for certain foods and for certain classes of importers. For example:

- Low-acid canned foods do not require FSVP activities for microbiological hazards when compliance is documented with the regulations concerning thermally processed low-acid foods packaged in hermetically sealed containers in Part 113.
- Importers of dietary supplements who are subject to the current good manufacturing regulations in Part 111 are not required to comply with the hazard analysis and FSVP requirements.
- Very small importers who document their eligibility prior to importation are not required to comply with the hazard analysis and FSVP including recordkeeping requirements in § 1.510 (§ 1.512).
- A very small importer is defined as having average annual sales of less than $1 million per year adjusted for inflation, of human food, during the 3-year period preceding the applicable calendar year (§ 1.500). With respect to animal food, a very small importer has average annual sales of less than $2.5 million.
- FSVP requirements are also modified for food from certain small foreign suppliers.
- Importers are not required to comply with the hazard analysis and FSVP for certain foods from countries that have an officially recognized food safety system (§ 1.513).
    - This applies to foods that are not intended for further processing.
    - Before importation and annually, the importer must document that the foreign supplier is under the regulatory oversight of a country whose food safety system is officially recognized by FDA as equivalent or comparable to that of the United States.

**FSMA – FSVP – Failure to Comply**

Admission will be refused to any article of food if it appears that the owner fails to comply with the FSVP Requirements in Subpart L.

## Lesson 2: Importation of Drugs

FDA regulates drugs for human consumption and its approval is required to sell drugs in the U.S. Regarding importation, section 505 of the FD&C Act (21 U.S.C. 355) prohibits the importation of unapproved new drugs, including foreign-made versions of U.S. approved drugs.

***Subject Drugs Include:***

- Prescription Drugs
- Over-the-Counter Drugs (OTC drugs)

**New Drug Approval**

- To bring a new drug to market, an applicant must submit a new drug application. An abbreviated new drug application can be filed for approval of a new drug that is the same as an existing approved drug.
- New drug approval is a highly technical process. The information that needs to be submitted includes, but is not limited to, chemistry, pharmacology, toxicology, and the results of statistical analyses and clinical trials.
- Drug approvals can be verified by searching the current edition of FDA's "Approved Drug Products with Therapeutic Equivalence Valuations," also known as the Orange Book. The Orange Book is found on the Drug Approvals and Databases page of the FDA website.

**Over-the-Counter Drugs Marketed without Pre-Approval**

- Certain over-the-counter drugs can be marketed without pre-approval, provided they comply with the requirements of 21 CFR Part 330 concerning over-the-counter human drugs which are generally recognized as safe and effective and not misbranded, and with the requirements of an OTC Monograph in 21 CFR Parts 331 - 358.
- An OTC Monograph is a regulation which provides specifications for a class of drugs.
    - For example, the Monograph for sunscreen drug products is found at 19 CFR Part 352. It includes a list of permissible active ingredients and their corresponding percentages, labeling requirements, and testing procedures.
- Format and content labeling requirements for over-the-counter drug products are listed at 21 CFR § 201.66. The labeling requirements of the applicable regulation or monograph must be followed when there is a conflict with the requirements of § 201.66.

**Personal Importations of Unapproved Drugs**

The FDA has issued guidance in Chapter 9 of the Regulatory Procedure Manual that FDA personnel should consider refraining from taking action against an individual who imports an unapproved drug product to continue a treatment that was begun outside of the United States for a condition for which there is no FDA approved treatment. The guidance applies under the following conditions:

- The treatment is not available domestically;
- There is no known promotion to persons residing in the United States by the persons distributing the product;
- The product does not represent an unreasonable risk;
- The individual affirms in writing that the treatment is for his own use;

- The patient provides the name and address of the doctor licensed in the United States who is supervising the treatment, or provides evidence that the product is for a treatment that was begun outside of the United States.

**Foreign Drug Establishments – Registration and Listing**

A drug establishment is defined as a place of business under one management at one general physical location that handles or works with a drug as defined in the Federal Food Drug and Cosmetic Act. The term includes, among others:

- Independent laboratories that engage in control activities for a registered drug establishment (e.g. consulting laboratories);
- Manufacturers of medicated feeds and of vitamin products that meet the above drug definition;
- Human blood donor centers;
- Animal facilities used for the production or control testing of licensed biologicals;
- Establishments engaged in salvaging.

Foreign drug establishments whose drugs are imported or offered for import into the United States shall comply with the establishment registration and drug listing requirements of 21 CFR Part 207, Subpart C, unless they are exempt under Part 207, Subpart B. The exemptions include:

- Pharmacies
- Hospitals
- Clinics
- Licensed practitioners
- Persons who use drugs solely for research, teaching, or chemical analysis
- Drug products that enter a foreign trade zone and export without entering U.S. commerce.

Foreign drug establishments are required to include in their registration the name of each importer in the United States and the name of each person who offers their drug for import into the United States [19 U.S.C. 360(i)(1)(A)].

- Owners or operators of establishments that engage only in distribution, under their own label or trade name, of a drug that was manufactured by a registered establishment, may elect to obtain a Labeler Code and submit listing information directly to FDA. Distributors who submit drug listing information to FDA assume full responsibility for compliance with all the requirements of Part 207.

Establishments must register within 5 days of beginning operations. In the initial registration the owner or operator of the drug establishment shall submit a list of every drug in commercial distribution at that time.

- Registration shall be renewed annually during the period from October 1st to December 31st (§ 207.21).
- Drug listing information shall be updated every June and December.
- Registration and listing is done electronically on FDA's Electronic Submission Gateway, unless a waiver is granted.
- Compliance with the establishment registration requirement can be verified by searching by firm name on FDA's Drug Establishments Current Registration Site.
- Verification of a drug listing can be done on the National Drug Code Directory, searching by proprietary name, application number, active ingredient, NDC number, or labeler.

**Biological Products**

Federal, international, and state laws strictly regulate shipping, transport, and import of biological materials. Federal and international regulations pertaining to the shipment of dangerous goods or hazardous materials may also apply to biological materials. Imports of biological materials must be clearly marked, labeled, packaged and/or placarded in accordance with the requirements of all international, Federal and state agencies.

Within the FDA, the Center for Biologics Evaluation and Research (CBER) regulates biological products such as:

- Blood
- Human Cells
- Vaccines

Compliance requirements in this area vary depending on the specific product. FDA's website provides information on CBER-Regulated Products which includes details for importers on the following requirements:

- Biologics License Application (BLA)
- Investigational New Drug Application (IND)
- Drug Establishment Registration (REG)
- New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)
- HCT/P Establishment Registration (HRN)

**Biological Products – When Not Regulated**

In certain circumstances, a biological specimen being imported may not be regulated by the FDA. For example:

- If the biological specimen is intended only for testing in a clinical laboratory or for basic scientific research and is not intended for the prevention, treatment, diagnosis, or cure of diseases, injuries, or conditions in human beings.

When a specimen is not regulated, a Customs broker/entry filer will need to "disclaim" FDA jurisdiction if the CBP HTS code allows.

## Lesson 3: **Importation of Medical Devices**

Medical devices are categorized into one of three classes depending upon the risk they present and the level of controls necessary to manage the risk. The medical device classification procedures are found in 21 CFR Part 860.

Class I represents the lowest risk. Devices are in Class I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Devices may still be classified in Class I when controls are not sufficient provided that the device is not life-supporting or life-sustaining and does not present a potential unreasonable risk of illness or injury.

Examples of Class I Devices include such items as pill crushers, bedpans, toothbrushes, and elastic bandages.

**Acceptable general controls include the provisions of the following sections of the FD&C Act:**

- Section 501 (21 U.S.C. 351), Adulterated drugs and devices;
    - A product is adulterated if it is contaminated with filth, or if it is mixed with another substance which results in a reduction of quality or strength.
- Section 502 (21 U.S.C. 352), Misbranded drugs and devices;
    - A device is misbranded if the label is misleading or if it lacks required directions or warnings
- Section 510 (21 U.S.C. 360), Registration of producers of drugs and devices;
- Section 516 (21 U.S.C. 360f), Banned devices;
- Section 518 (21 U.S.C. 360h), Notification and other remedies;
- Section 519 (21 U.S.C. 360i), Records and reports on devices;
- Section 520 (21 U.S.C. 360j), General provisions respecting control of devices intended for human use.

**Class II r**epresents moderate risk. Devices are in Class II if general controls alone are insufficient to provide reasonable assurance of their safety and effectiveness and there is sufficient information to establish special controls. Examples of Class II Devices include such items as suction catheters, sharps containers, acupuncture needles, and infusion pumps.
Special controls include the following:

- Promulgation of performance standards
- Postmarket surveillance
- Development and dissemination of guidance documents

- Recommendations
- Other appropriate actions as the FDA Commissioner deems necessary to provide such assurance

**Class III** represents the highest risk. Devices are in Class III if insufficient information exists to determine if general controls or special controls are sufficient to provide assurance of their safety and effectiveness, and if the device is life sustaining or presents a potential unreasonable risk of illness or injury.

Examples of Class III Devices include:

- Defibrillators
- Chemical snake bite kits
- Heart valves
- Pacemaker batteries

There are several options for finding the classification of a device.

- One is to search the FDA Product Classification Database by device name, product code, or regulation number. Drop-down menus allow for searching by review panel, submission type, or device class.
- Another option is to search the Classification Panels on the FDA website. Classification Panels are medical specialties into which products are categorized. Examples of specialties include dental, ear nose and throat, general hospital, and pathology. Clicking on the applicable specialty opens up a list of the devices categorized within that specialty.

**Premarket Submission**

The type of premarket submission required is determined by class. Class I and Class II devices require premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360). Most Class III devices require premarket approval under section 515 of the FD&C Act (21 U.S.C. 360e).

*Exemptions*:

- 21 CFR Parts 862 through 892 lists exemptions for many Class I and Class II devices, provided the product does not exceed the limitations listed.
- Certain Class I devices are also exempt from the current good manufacturing practice requirements of the quality system regulation in Part 820.
- FDA has a listing on the Medical Device Exemptions page of their website of devices that are exempt from premarket notification.

**Device/Establishment Registration – Required Timeline**

U.S establishments (as defined by FDA) that are first time importers must register with FDA prior to the importation of the device.

Foreign establishments (e.g. manufacturers and exporters) must register with FDA and also list their devices. The initial registration of a foreign establishment must occur before devices are exported to the United States.

**Device/Establishment Registration – Electronic Submission**

Registration is done electronically using FDA's United Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM).

When registering for the first time, an Initial Importer will identify the manufacturer of the products they import by using either the manufacturer's device listing number, establishment registration number, or establishment name and address.

After identifying the manufacturer, the importer will select the devices they are importing from the manufacturer's registration information.

An official correspondent must also be designated and is responsible for the annual registration of the facility and listing of devices. The official correspondent also receives correspondence from the FDA and facilitates communication between the establishment's management and representatives of FDA.

**Device/Establishment Registration – Annual Requirements**

Establishments must register annually between October 1 and December 31, even if no changes have occurred. Device listing information must be reviewed between October 1 and December 31.

Updates, if any, can be submitted when submitting establishment registration information.

Updates can be submitted at any time for the following changes:

- A new device is introduced;
- A previously listed device is changed;
- A device is removed from distribution or distribution is resumed;
- An initial importer changes manufacturers;
- A foreign establishment changes importers.

**Foreign Establishment – U.S. Agent Required**

A foreign establishment must have a U.S. agent and submit the name, address, and phone number of such as part of its initial and updated registration information.

- The agent may also be designated as the official correspondent.
- The U.S. agent must reside or maintain a place of business in the United States.

- The U.S. agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products, and assist FDA in scheduling inspections.
- If FDA is unable to contact the foreign establishment directly, providing information or documents to the U.S. agent will be considered to be equivalent to providing the same information or documents to the foreign establishment.

## Lesson 4: Importation of Radiation-Emitting Devices

Electronic products that emit radiation are regulated by FDA under Chapter IV, Part C of the FD&C Act (21 U.S.C. 360hh *et. seq.*). Electronic products that emit radiation are those that contain or act as part of an electronic circuit and emit electronic product radiation, or would emit electronic product radiation in the absence of effective shielding or other controls [21 CFR § 1000.3(j)].

Radiation can be emitted in the following forms:

| Ionizing | Optical | Radio Frequency, Microwave, Magnetic | Acoustic |
|---|---|---|---|
| Medical X-Ray | Surgical Laser | Microwave Oven | Ultrasound Imaging |
| Dental X-Ray | Laser Welder | Radar | Doppler Ultrasound |
| Mammography | Laser Material Processing | Magnetic Resonance Imaging (MRI) | Hearing Aid |
| Industrial X-Ray | Laser Light Show | Sterilizer (Plasma) | Pest Repeller |
| Security X-Ray | Laser Printer | Remote Controller | Motion Detector |
| Fluoroscopy | CD Player | Microwave LAN | |
| | Suntan Bed | | |

Some products are subject to performance standards. These products are indicated in Table 1 of § 1002.1 by a reference in parenthesis to the applicable section. Performance standards are found in following parts of 21 CFR:

- Part 1010 – Performance Standards for Electronic Products: General
- Part 1020 – Performance Standards for Ionizing Radiation Emitting Products

- Part 1030 – Performance Standards for Microwave and Radio Frequency Emitting Products
- Part 1040 – Performance Standards for Light-Emitting Products
- Part 1050 – Performance Standards for Sonic, Infrasonic, and Ultrasonic Radiation Emitting Products

Certain products, prior to introduction into the commerce of the United States will require filing of a product report (§ 1002.10) or an abbreviated report (§ 1002.12).

Table 1 of § 1002.1 specifies which reports are required for each of the listed products. The product report provides detailed technical information about the product, including all components and accessories that may have an effect on safety.

Information on testing and safety procedures is required. The contents of warning signs and labels must be reported. The abbreviated report will include a brief description of operational characteristics that affect radiation emissions or control exposure.

Many of the products that require a product report will require a supplemental report when changes are made that affect radiation emission or the manner of compliance with a standard or manner of testing for radiation safety.

Annual reports are required for many of the products listed in Table 1 (§ 1002.13). Annual reports summarize the contents of required records and provide information on production of the covered products. Reports are due by September 1 for the 12-month period ending on June 30 preceding the due date of the report.

Where guides or instructions have been issued by FDA for the submission of reports, the material submitted must conform to the requirements of those guides or instructions [§ 1002.7(b)]. Guidance documents can be found on the FDA website.

FDA will respond to a report by sending an acknowledgement of receipt letter to the manufacturer. The letter will include a unique reference number known as an accession number. The accession number is not an approval of the product. It is an acknowledgment that the required report has been received and is now stored in the database.

Customs entries of electronic products subject to radiation control standards require FDA Form 2877. Form 2877 is used by importers for declaration that a product is admissible for one of the following reasons:

- The product is not subject to radiation performance standards due to one of the reasons in Section A of the form.

- The product complies with applicable performance standards. The accession number of the last annual report or product report is required.
- The product does not comply with performance standards, but is being imported temporarily under bond, and will be exported or destroyed. This provision may be used for research or for demonstration purposes.
- The product does not comply with performance standards, but will not be introduced into commerce until notification is received from FDA that the product has been brought into compliance in accordance with an FDA approved petition.

## Lesson 5: **Importation of Cosmetics**

Cosmetics are articles which are applied to the human body for the purpose of cleansing, beautifying, promoting attractiveness, or altering the appearance [21 U.S.C. 321(i)]. The definition includes articles that are used as components of cosmetics.

Examples of cosmetics:

- Skin moisturizers
- Perfumes
- Lipsticks
- Makeup
- Deodorant
- Shampoo

Companies that manufacture or import cosmetic products are not required to register with the FDA. Cosmetic products do not require listing.

FDA does not regulate soap, unless the soap is antibacterial. FDA interprets the term "soap" to apply to articles that meet the following conditions:

- The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and
- The product is labeled, sold, and represented only as soap (21 CFR § 701.20).

Products that meet the definition of soap are regulated by the Consumer Product Safety Commission. Cleansing products that do not meet the definition of soap are considered to be cosmetics.

Some cosmetic articles are also drugs. If a cosmetic product is also intended to cure, treat, or prevent disease, or to affect the structure or any function of the human body, it will need to comply with the requirements for drugs and the requirements for cosmetics.

Examples are:

- Deodorants which are also antiperspirants
- Shampoo that also treats dandruff
- Toothpaste that contains fluoride

**Color Additives**

- Color additives are dyes, pigments, and other substances, which are used to impart color to a cosmetic product or to the human body [§ 70.3(f)].
- Color additives require premarket approval [21 U.S.C. 379e(a)]. Some color additives, primarily those obtained from petroleum sources, also require batch certification by the laboratory of the FDA Color Certification Branch [21 U.S.C. 379e(c)].
- FDA issues a specific regulation, known as a Listing Regulation for each color additive that it approves. FDA approval can be verified by referencing the Listing of Color Additives Exempt from Certification in Part 73, or the Listing of Color Additives Subject to Certification in Part 74. The regulations provide identity, specifications, approved uses, and labeling requirements.
- Certification can be verified by reference to the certificate issued by the FDA showing the lot number they assigned to the batch. Certified color additives are required to show the lot number on the labeling [§ 70.25(d)].
- An exemption exists for hair dyes that contain color additives from coal-tar sources [21 U.S.C. 361(a)]. They do not require approval and certification. The following warning must appear on their labeling:

  > "Caution-This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

- The label must also provide adequate directions which an individual can use to conduct a preliminary test for skin irritation.

**Adulterated or Misbranded Cosmetics**

The FD&C Act prohibits the importation of cosmetic products that are adulterated (21 U.S.C. 361) or misbranded (21 U.S.C. 362).

A cosmetic is adulterated if:

- It bears any poisonous or deleterious substance;
- It consists in whole or in part of any filthy, putrid, or composed substance;

- It has been held, packed, or prepared under insanitary conditions in which the product may have been contaminated;
- The container is composed in whole or in part of any poisonous or deleterious substance which may have rendered the product injurious to health;
- It bears or contains an unsafe color additive.

A cosmetic product is considered misbranded if:

- Its labeling is false or misleading;
- Its label does not include all required information;
- The required information is not adequately prominent and conspicuous;
- Its container is so made, formed, or filled as to be misleading;
- It is a color additive, other than a hair dye, which does not conform to applicable regulations concerning listing and certification of color additives;
- Its packaging or labeling does not comply with the requirements of section 3 or 4 of the Poison Prevention Packaging Act of 1970.

**Labeling Requirements**

- Detailed requirements concerning the content and form of labels are found in Part 701. The required information includes identity of the product by common or usual name, ingredients listed in descending order, identity of manufacturer or distributor, and net quantity.
- Certain products, such as self-pressurized containers, feminine deodorant spray, and foaming bath detergent are required to have warning statements on the labels (Part 740). Cosmetic products contained in aerosol spray cans must bear the following warning:

  "Warning-Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F. Keep out of reach of children."
- A labeling exemption exists for bulk shipments of cosmetics when the importer is also the operator of the facility which will package and label the cosmetic product. When the importer is not also the operator of the facility, there must be a written agreement between the importer and the operator of the facility which contains specifications for the processing, labeling, and repacking of the cosmetic product.

**Prohibited Ingredients**

A manufacturer may use any ingredient provided that the ingredient and the finished cosmetic are safe under labeled or customary conditions of use. However, certain ingredients are prohibited by regulations.

Prohibited ingredients include, but are not limited, to the following:

- Bithionol is prohibited because it may cause photo-contact sensitization (§ 700.11);

- Chlorofluorocarbon propellants are prohibited as ozone depleting substances (§ 700.23), (§ 2.125);
- Chloroform is prohibited because of its animal carcinogenicity and likely hazard to human health (§ 700.18);
- Methylene chloride is prohibited because of its animal carcinogenicity and likely hazard to human health (§ 700.19);
- Vinyl chloride is prohibited as an ingredient of aerosol products because of its carcinogenicity (§ 700.14);
- Certain specified risk material from cattle, material from nonambulatory disabled cattle, and material from cattle that has not passed inspection are prohibited to prevent mad cow disease (§ 700.27).

**Examination of Imported Cosmetics**

Imported cosmetics are subject to examination by CBP at the time of entry. Foreign cosmetics that appear to be adulterated or misbranded may be refused entry into the United States.

Common reasons for refusal are:

- Unsafe ingredients or contaminants;
- Color additives that are not approved, or not approved for the intended use;
- Color additives not from a certified batch;
- Prohibited and restricted ingredients;
- Labeling violations;
- Claims that cause a cosmetic product to be subject to regulation as a drug.

## Lesson 6: Importation Procedures

Products subject to FDA require release by both CBP and FDA.

**CBP Release**

Release from CBP custody of any product that is subject to FDA regulation under the FD&C Act is deemed conditional. The conditional release period will end upon the earliest occurrence of one of the following events:

- The date that FDA issues a notice of refusal of the merchandise;
- The date that FDA issues a notice that the merchandise may proceed;
- Upon the end of the 30-day period following the date of release.

The conditional release period may be extended. The FDA must issue a notice of sampling, detention, or other FDA action to the importer for extension of the release period to occur.

If FDA issues a notice of refusal, or if any notice of sampling or other request is not complied with, CBP will issued a demand for redelivery within **30 days** of the date of the notice of refusal or the date FDA determined noncompliance with any request. Failure to redeliver the product will result in assessment of liquidated damages of three times the value of the merchandise involved unless the port director has prescribed a bond amount equal to the domestic value of the merchandise pursuant to 19 CFR § 12.3(b).

Entries that are not given the "May Proceed" during the automated screening process will be reviewed by an FDA District entry reviewer.

The entry reviewer may request additional documents. Although documents can be submitted in paper form to the FDA District office, FDA recommends that they be submitted through the Import Trade Auxiliary Trade Communications System (ITACS), https://itacs.fda.gov. After reviewing the documents, the entry reviewer can release the product, request a sample or an examination, or recommend to the Compliance Branch that the article be detained.

If the entry reviewer determines that there is no need for further review, the "May Proceed" will be issued manually in an ABI response.

**FDA Release**

Entries of FDA regulated products that are transmitted via ACE will be screened automatically by the FDA system known as PREDICT. The accuracy of information submitted is of great importance. Submitting accurate identifiers of firms and correct FDA Product Codes along with relevant Affirmations of Compliance may enable the system to automatically issue a "May Proceed." However, that is not guaranteed, as an entry may be subject to further review due to routine surveillance or other screening criteria.

When admissibility cannot be determined by a review of the documents or an examination, the shipment may be detained.

The reasons for detention include the following:

- History of violations;
- Lack of required documents;
- Incorrect documents;
- Documents inconsistent with entry declarations.

Detention is an administrative process. The shipment can be moved to the importer's facility. However, the product may not be distributed.

FDA will issue a Notice of Action with the following information:

- Belief that the article is subject to refusal;
- Reasons for refusal;
- Right of importer to provide testimony;
- Timeframe for response;
- Contact information.

The importer may present testimony, such as laboratory analysis which shows that the article is in compliance. Or they could show that the article is not intended for a use that would cause it to be subject to the FD&C Act.

**Reconditioning**

The importer can petition to recondition the product. For example, if a product found during examination to contain sulfites is not properly labeled, the importer may petition to relabel the article to state that it contains sulfites. Adulterated articles can be cleansed. An article can be converted from food use to industrial use which would be outside the jurisdiction of the FD&C Act.

- The procedure for petitioning to recondition is to submit FDA Form 766 to the Compliance Officer named in the Notice of Action. The importer shall also submit a reconditioning plan of action, or copies of the current and proposed labels. The regulations concerning reconditioning are in 21 CFR Part 1, Subpart E. FDA provides guidance on reconditioning in Section 9-10 of the Regulatory Procedure Manual.
- In the **Proposal** Section of Form 766, the importer shall provide detailed information on how the article will be brought into compliance or how the article will be rendered not a food, drug, device, or cosmetic. A proposal for fumigation should specify the fumigant, the method, and the duration of application. The time and place where the operations will be carried out shall be specified along with the approximate time for their completion. An acceptable disposition of rejects shall be proposed.
- The **Action on Application** Section is used by the FDA in either approving or disapproving the application. Applications should be approved only if it appears that the relabeling or other action will result in an acceptable product.

After performing the approved operations, the importer will advise FDA in the **Importer's Certificate** Section that the approved operations have been performed and the article is available for inspection. The article must be held intact pending FDA's determination of the adequacy of the reconditioning.

The examining CBP or FDA officer will document the results in the **Report of Inspector** section. That section will later be used in preparing the Release Notice or the Notice of Refusal of Admission.

When an applicant is unsuccessful in their attempt to recondition an adulterated shipment, they may submit a second application. However, the application should not normally be approved unless it contains meaningful changes in the reconditioning process. The Regulatory Procedure Manual advises that the following statement included in the Action on Application section when approving a second application:

> "IF THIS ATTEMPT AT RECONDITIONING DOES NOT BRING THE MERCHANDISE INTO COMPLIANCE FUTURE APPLICATIONS TO DO SO MAY NOT BE CONSIDERED."

The Regulatory Procedure Manual further advises that requests for a third attempt at reconditioning generally should not be granted since allowing unlimited attempts at reconditioning would encourage importers to import grossly adulterated merchandise into the United States.

## CONCLUSION

The FDA authority covers a significant number of products and often involves detailed knowledge to properly license, update and import products.

Non-compliant imports can be subject to hold, seizure, re-exportation or destruction as well as incur elevated penalties.

Brokers should work with customers to ensure they have the right information, assign the correct FDA product codes, affirmation of compliance codes, etc. at the time of import.