

## U.S. Medical Devices Market

Medical equipments represent a wide range of health care products used by physicians to diagnose and treat patients in inpatient and outpatient settings. These range from tongue depressors, to highly sophisticated diagnostic devices that can provide clear images of internal organs.

In the U.S., medical and dental instruments and supplies include five specific industries: surgical and medical instruments (SIC 3841); surgical appliances and supplies (SIC 3842); dental equipment and supplies (SIC 3843); X-ray apparatus and tubes (SIC 3844), and electromedical equipment (SIC 3845). It also includes diagnostic products, classified under In Vitro and In Vivo Diagnostic Substances (SIC 2835); surgical gloves, condoms, and similar latex based products, under Fabricated Rubber Products, Not Elsewhere Classified (SIC 3069).

In the U.S. market, growth levels are driven by national health care expenditures. These include the costs of new regulatory requirements to ensure product safety and effectiveness, and changes in insurance coverage. An example of the former is the **1990 Safe Medical Devices Act**, which redefined many of the procedures for bringing medical devices to the market. Meanwhile, insurance programs have dictated the need for medical providers to purchase capital items such as computed tomography scanners (CT) and other high-cost radiology products.

### Medical Device Regulations

The Safe Medical Devices Act of 1990 established requirements for manufacturers to ensure that products entering the market are safe and effective, particularly in the areas of premarket approval and postmarket surveillance. For example, premarket notification applications, commonly referred to as **510(k)s**, for certain types of medical equipment must include a summary of safety and effectiveness data or state that such information is available upon request. The law also requires that for high risk devices introduced after 1990, manufacturers must conduct postmarket surveillance.

The Food and Drug Administration (FDA) also may require postmarket surveillance for any other device if the agency believes this action is necessary to protect public health. Other provisions of the law call for regulating hybrid products, which are a combination of device, drug, or biologic; track distribution and end use of certain devices; and require hospitals and other end-users to report deaths associated with faulty medical devices. The law also calls for stricter FDA enforcement. Any manufacturers that are not in full

compliance with specified good manufacturer practices may face civil penalties, recalls, or cessation of shipments.

## **Technology**

Over the years it has become increasingly difficult to receive premarket clearance [510 (k)s] by the FDA, and the time to process product approvals by the FDA has increased. Nevertheless the U.S. industry continues to develop new products and to devote increasing resources to R&D.

## **U.S. Market**

Hospitals, the largest end-users of medical equipment, face extreme pressures by the government and other third-party payers to curtail rising health care expenditures. These cost containment efforts have affected the overall financial status of the hospital industry. Total hospital margins have been affected. As a result, health care delivery will continue to change, which, in turn, will determine the types of products purchased by hospitals and other end-users. For example, inpatient admissions have declined while outpatient visits have grown.

The supply of competing providers like ambulatory surgical centers, urgent care centers, comprehensive outpatient rehabilitation facilities, and diagnostic imaging centers have increased rapidly, and are providing significant new markets for medical equipment. In addition, items for home care, such as nutritional therapy products are growing.

## **Importing Medical Devices into the U.S.**

Foreign firms that manufacture medical devices and/or products that emit radiation that are imported into the United States must comply with applicable U.S. regulations before, during, and after importing into the U.S. or its territories. In order to import medical devices and/or products that emit radiation into the U.S., the product must meet FDA regulatory requirements. FDA does not recognize regulatory approvals from other countries. The following is a summary of FDA requirements for medical devices and products that emit radiation.

### Foreign Manufacturers

Foreign manufacturers must meet applicable United States (U.S.) medical device regulations in order to import devices into the U.S. even if the product is authorized for marketing in another country. These requirements include

registration of establishment, listing of devices, manufacturing in accordance with the quality system regulation, medical device reporting of adverse events, and Premarket Notification 510(k) or Premarket Approval, if applicable. In addition, the foreign manufacturers must designate a United States agent (See <http://www.fda.gov/cdrh/usagent/>) for full details).

### How to Locate a United States agent?

The U.S. Government recognizes that foreign firms might have difficulty in finding a United States agent. Therefore, as a service, we maintain a database accessible through the FDA website to assist foreign establishments in locating United States agents.

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfUSagent/search.cfm>).

Any person who wants to be a United States agent for a foreign establishment may enter into the database his or her name, address, and contact information. The information in the United States agent database has been submitted directly by those persons offering their services as a United States agent.

It should be noted that FDA does not endorse the use of any of the persons whose name appears in this database. When contacting the person or persons offering their services as a United States agent, it is important to recognize that some persons or firms may offer additional services that are not required by the registration and listing regulation.

As with domestic manufacturers, foreign manufacturing sites are subject to FDA inspection. Information on U.S. regulatory requirements can be found on the Device Advice website (<http://www.fda.gov/cdrh/devadvice/>), information given therein as follows:

▶ Overview of Regulations	▶ Investigational Device Exemptions (IDE)
▶ Is Your Product Regulated?	▶ Premarket Approval
▶ Classify Your Device	▶ Quality Systems
▶ How to Market Your Device	▶ Medical Device Labeling
▶ Does Your Product Emit Radiation?	▶ Medical Device Reporting
▶ Registering Your Establishment	▶ Medical Device Recalls
▶ Listing Your Device	▶ Importing Devices ▶ Exporting Devices
▶ Premarket Notification 510(k)	▶ Medical Device Tracking
▶ 510(k)/GMP Exemption	▶ Postmarket Surveillance Studies

## Initial Importers

The initial importer of the device must register its establishment with FDA. An initial importer is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. Registration information, including the registration form FDA-2891, can be found under Establishment Registration.

(See <http://www.fda.gov/cdrh/devadvice/341.html>).

### **What is Establishment Registration?**

Establishments involved in the production and distribution of medical devices intended for marketing or leasing (commercial distribution) in the United States (U.S.) are required to register with the FDA. This process is known as establishment registration. Registration provides FDA with the location of medical device manufacturing facilities and importers. The regulations for establishment registration are provided in 21 CFR 807. No registration fee is required. An *establishment* means any place of business under one management at one physical location at which a device is manufactured, assembled or otherwise processed for commercial distribution. The "owner/operator" of the establishment is responsible for registration. *Owner/operator* means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

Registration of an establishment is not an approval of the establishment or its devices by FDA. That is, it does not provide FDA clearance to market. Unless exempt, premarketing clearance is required before a device can be placed into commercial distribution in the U.S.

Misbranding by Reference to Establishment Registration Number: Title 21 of the Code of Federal Regulations, Section 807.39, states, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." Product labeling and Internet sites cannot reference your establishment registration number or make reference to your establishment being registered or approved by FDA. If your product labeling or Internet sites list your establishment registration number or makes reference to your establishment being registered and approved by the FDA, then these references must be removed.

## **Who Must Register?**

### Manufacturers

An owner/operator of an establishment not exempt under 21 CFR 807.65 who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a medical device intended for commercial distribution (marketing) is required to register on form FDA 2891, Registration of Device Establishment, (21 CFR 807.20). This includes manufacturers, contract manufacturers, contract sterilizers, specification developers, repackagers or relabelers, reprocessors of single-use devices, remanufacturers, U.S. manufacturers of export only devices, and manufacturers of components or accessories that are sold or leased directly to the end user.

### Initial Importers

An initial importer (or initial distributor) takes first title to the devices imported into the U.S. and further distributes the product. Initial importers are required to register. However, they are NOT required to list the products that they import on form FDA 2892. Wholesale distributors of devices, who do not manufacture, repack, process, or relabel a device, are not required to register their establishment with the FDA. A "wholesale distributor" is defined as any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

### Foreign establishments (manufacturers and exporters)

Foreign establishments that manufacture, prepare, propagate, compound, or process a device that is imported, or offered for import, into the U.S. are required to register their establishments on form FDA 2891. This includes contract manufacturers and contract sterilizers. Foreign establishments must also list the devices that they export to the U.S. on the listing form FDA 2892.

In addition, foreign establishments must provide FDA with the name, address, phone and fax numbers, and email address of the United States agent representing their establishment. The requirement for foreign manufacturers and exporters to register and identify a United States agent became effective February 11, 2002.

## **United States Agent for Foreign Establishments**

Effective February 11, 2002, all foreign establishments must notify FDA of the name, address, phone and fax numbers, and email address of their United States agent. Even if an establishment manufactures various medical devices, drugs, and/or biological products, each establishment can identify only one United States agent. The United States agent must either reside in the U.S. or maintain a place of business in the U.S. The United States agent cannot use a post office box as an address. The United States agent cannot use an answering service. The agent must be available to answer the phone or have an employee available to answer the phone during normal business hours. The Official Correspondent for registration may also be the United States agent for the establishment, but this is not required.

### **Responsibilities of United States Agent**

- Assisting FDA in communications with the foreign establishment,
- Responding to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and
- Assisting FDA in scheduling inspections of the foreign establishment.

In addition, if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered equivalent to providing the same information or documents to the foreign establishment. The United States agent has no responsibility to report adverse events under the Medical Device Reporting regulation (21 CFR Part 803), or to submit Premarket Notifications [510(k)] (21 CFR Part 807, Subpart E).

Source: [http://www.fda.gov/cdrh/devadvice/341.html#link\\_1](http://www.fda.gov/cdrh/devadvice/341.html#link_1)

Initial importers are also subject to Medical Device Reporting (MDR) (<http://www.fda.gov/cdrh/devadvice/351.html>) under 21 CFR 803, Reports of Corrections and Removals under 21 CFR 806, and Medical Device Tracking (<http://www.fda.gov/cdrh/devadvice/51.html>) under 21 CFR 821, if applicable. Under the MDR regulations importers are required to report incidents in which a device may have caused or contributed to a death or serious injury as well as report certain malfunctions. The importers must maintain an MDR event file for each adverse event. All product complaints (MDR and nonMDR events) must be forwarded to the manufacturer. Under Medical Device Tracking requirements, certain devices must be tracked through the distribution chain.

## **Products that Emit Radiation**

Foreign manufacturers that export electronic products (medical device or non-medical) that emit radiation to the United States are subject to the requirements of the Federal Food, Drug, and Cosmetic Act, Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968). These requirements include performance standards, labeling, and submission of radiation safety product reports. Guidance on these requirements can be found on the Internet under Electronic Product Radiation Control (<http://www.fda.gov/cdrh/comp/eprc.html>). When manufacturers submit radiation safety product reports, the reports are entered into a database and assigned an accession number (file point). Importers may submit radiation safety product reports on behalf of manufacturers. For further information on how to market a product in the U.S., refer to the Device Advice website at:

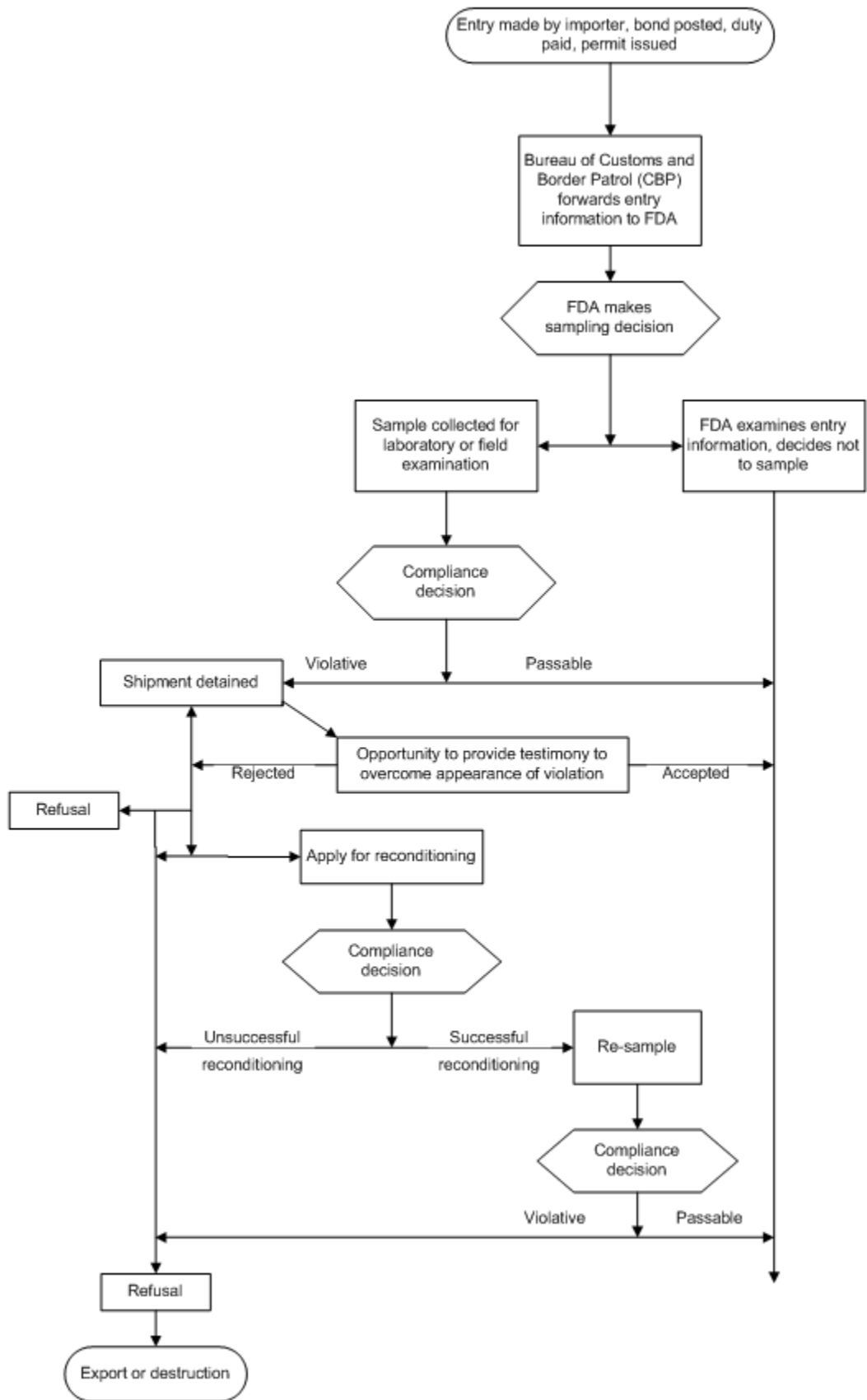
<http://www.fda.gov/cdrh/devoadvic/overview.html>

## **Import Process**

All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) ([www. customs.ustras.gov/xp/cgov/import](http://www.customs.ustras.gov/xp/cgov/import)) requirements in addition to FDA. Products that don't meet FDA regulatory requirements may be detained upon entry.

The major responsibility of CBP is to administer the Tariff Act of 1930 as amended. Primary duties include assessment and collection of all duties, taxes, and fees on imported merchandise; administration and review of import entry forms; the enforcement of CBP and related laws; and administration of certain navigation laws and treaties. There is a working agreement between FDA and CBP for the cooperative enforcement of Section 801 of the FD&C Act.

The import process, as shown in the "Import Procedures Flowchart" below, begins with the importer or filer submitting the necessary entry information to the local CBP district office. For those entries not filed electronically, a paper entry consisting of the commercial invoice, CBP entry forms CF3461/3461ALT and/or CF7501 or documentation that would need to be provided by the importer or filer. (See import procedures flowchart below).





Entry information should identify the product and include appropriate information to demonstrate that the product is in compliance with FDA regulations. Product information should include device name and product code (as provided on the Device Listing form, FDA-2892). The affirmation of compliance should include: importer registration number, foreign establishment registration number and name of U.S. agent, medical device listing number, and Premarket Notification 510(k) or Premarket Approval number, if applicable. Please note that the product code provided to CBP must include a two-digit prefix identifying the medical specialty in addition to the three-letter code that was submitted on the FDA-2892. The medical specialty codes are as follows:

<b>Number</b>	<b>Medical Specialty</b>	<b>Regulation</b>
73	Anesthesiology	Part 868
74	Cardiovascular	Part 870
75	Chemistry	Part 862
76	Dental	Part 872
77	Ear, Nose, and Throat	Part 874
78	Gastroenterology and Urology	Part 876
79	General and Plastic Surgery	Part 878
80	General Hospital	Part 880
81	Hematology	Part 864
82	Immunology	Part 866
83	Microbiology	Part 866
84	Neurology	Part 882
85	Obstetrics and Gynecology	Part 884
86	Ophthalmics	Part 886
87	Orthopedics	Part 888
88	Pathology	Part 864
89	Physical Medicine	Part 890
90	Radiology	Part 892
91	Toxicology	Part 862

For example, the device product code provided to CBP for sunglasses would be 86HQY. Classify your medical products on FDA's Device Advice website at: (<http://www.fda.gov/cdrh/devadvice/313.html>)

Importers of radiation emitting electronic products subject to a federal performance standard are required to submit a written declaration on "Declaration of Products Subject to Radiation Control Standards," form FDA-

2877, (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2877.pdf>) along with other import entry information, including accession number, if appropriate, through CBP to the appropriate FDA district office. Electronic products that fail to comply with the applicable performance standard or do not have a certification label or tag (21 CFR 1010.2) affixed to each product shall be refused. (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1010.2>)

Most importers ask that domestic customhouse brokers (or filers) complete these forms electronically and make the submissions on their behalf. Filers have access to the Operational and Administrative Systems for Import Support (OASIS), the FDA computerized import system. The OASIS program is an electronic interface between FDA and the CBPs Automated Commercial System (ACS). OASIS is an on-line interactive and automated system, which replaced the process of reviewing the paperwork for import entries manually.

When an entry is filed with CBP, a copy of the entry is also provided to the local FDA district office. The FDA district office then determines if the product complies with FDA requirements. The FD&C Act authorizes FDA to detain a regulated product that appears to be out of compliance with the Act. If a product appears to be out of compliance, the FDA district office will issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee. The owner or consignee is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product. If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue another "Notice of FDA Action" refusing admission to the product. The product then has to be exported or destroyed within 90 days. Failure to do so within 90-days may result in issuance of a Customs Redelivery Notice and an assessment for liquidated damages for up to 3 times the value of the lot.

Upon entry, FDA may examine certain devices to assure their safety and effectiveness. When this occurs, FDA will issue a notice to the importer of a record on a form titled "Notice of FDA Action." Sampling may involve examining the product at the port of entry or physical collection of a statistical portion of the lot for analysis by an FDA laboratory. If the sample is violative, or if the sample is determined to be out of compliance with required specifications, the device will be detained and the importer of record will be issued a "Notice of FDA Action" indicating that the article is being detained due to the appearance of a violation under the FD&C Act. The "Notice of FDA Action" will state the specific violations to the FD&C Act.

Under certain conditions, the importer of record of a device that has been detained is given an opportunity to submit application for authorization to bring

the device into compliance with the FD&C Act. If FDA permits reconditioning, another sample may be collected and analyzed after reconditioning. If the device is then determined to be in compliance, it will be released. The FDA District Office ([http://www.fda.gov/ora/inspect\\_ref/iom/IOMORADIR.html#orafield](http://www.fda.gov/ora/inspect_ref/iom/IOMORADIR.html#orafield)) at the port of entry has the authority to authorize reconditioning and/or to release the shipment. You must provide the appropriate documentation or bring the products into compliance under authorization from the District Office. When contacting the District Office, you should ask for the Compliance Office and provide the entry number and/or sample number as a reference.

Additional information on importation of medical devices can be found in the following documents:

- **Regulatory Procedures Manual, Chapter 9, Import Procedures**  
[http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9imp.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9imp.html)
- **FDA Investigations Operations Manual, Chapter 6, Imports**  
[http://www.fda.gov/ora/inspect\\_ref/iom/contents/ch6\\_toc.html](http://www.fda.gov/ora/inspect_ref/iom/contents/ch6_toc.html)
- **Import Alerts**  
[http://www.fda.gov/ora/fiars/ora\\_import\\_alerts.html](http://www.fda.gov/ora/fiars/ora_import_alerts.html)
- **Import Program System Information**  
[http://www.fda.gov/ora/import/ora\\_import\\_system.html](http://www.fda.gov/ora/import/ora_import_system.html)

### **Import for Export**

A firm may import device parts, components, subassemblies, etc. for further processing or incorporation into unapproved devices that are to be subsequently exported. A firm *may not* import a *finished* unapproved device without prior marketing clearance, even if the device is to be imported solely for subsequent export. The terms "further processing" and "incorporation" as detailed in the **FDA Guidance for Industry** is broad in its interpretation ([http://www.fda.gov/ora/import/ora\\_import\\_system.html](http://www.fda.gov/ora/import/ora_import_system.html)). For example, a device imported for further packaging or labeling would fall into this category; a device which is simply stored without any further action prior to export would *not* fall into this category.

The provisions for import for export under section 801 of the FD&C Act have been amended by the **Section 322 of Bioterrorism Act of 2002**. Importers wishing to import devices (including components or an accessory of a device or other article of a device requiring further processing, which is ready or suitable

for use for health-related purposes) that are intended for further processing or incorporation into another product and subsequent export must provide FDA with certain information at the time of initial importation. The information includes a statement that confirms the intent to further process such article or incorporate such article into a product to be exported and identifies entities in the chain of possession of the imported article. At the time of initial importation and before delivery to the importer, initial owner, or consignee, a bond must be executed providing for liquidated damages in the event of default, in accordance with Bureau of Customs and Border Protection (formerly called U.S. Customs) requirements. The initial owner or consignee of the article must maintain records of the use and/or destruction of such imports and must submit the records or a report to FDA upon request. Additional guidance on import for export can be found in Chapter 9 of the Regulatory Procedures Manual, Import for Export. ([http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9impex.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9impex.html))

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## **Import Regulation References**

- Regulatory Procedures Manual, Chapter 9, Import Operations/ Actions
- FDA Investigations Operations Manual, Chapter 6, Imports
- Import Alerts
- Import Program System Information
- FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.
- Food Drug &Cosmetic Act

## **Compliance Policy Guides**

- Export of FDA Regulated Products from U. S. Foreign Trade Zones, Compliance Policy Guide, Section 110.200 (CPG 7150.11)
- Food and Drug Guaranty - Imports, Compliance Policy Guide, Section 110.500 (CPG 7153.10)
- FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers, Compliance Policy Guide, Section 110.600 (CPG 7150.14)
- Seizures by the U. S. Customs Service of Prohibited Articles of Foreign Origin Not Intended for Entry into the United States, Compliance Policy Guide, Section 110.700 (CPG 7153.08)
- Imports, Post Detention Sampling, Compliance Policy Guide, Section 110.800 (CPG 7150.04)
- Imported Products - Lack of English Labeling, Compliance Policy Guide, Section 110.900 (CPG 7150.15)

## Regulations 21 CFR 1, Subpart E--Imports and Exports

- [§1.83](#) - Definitions.
- [§1.90](#) - Notice of sampling.
- [§1.91](#) - Payment for samples.
- [§1.94](#) - Hearing on refusal of admission.
- [§1.95](#) - Application for authorization to relabel and recondition.
- [§1.96](#) - Granting of authorization to relabel and recondition.
- [§1.97](#) - Bonds.
- [§1.99](#) - Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

## Business References

### How to find direct buyers?

While there is no substitute for the knowledge and industry contacts of experts on the ground who may partner with Pakistani suppliers as their distributors or agents in the U.S. market, there are limited resources available that are for sale that provide resources for identifying buyers. Such resources are typically databases that are compiled based on information about subscribers to various technical publications. It is assumed that such entities may have an interest in selected goods or services. It should be noted that there is no way of obtaining data on who actually purchased various goods or services. Rather, databases that are offered for sale provide contact information for subscribers of technical publications and by virtue of this are assumed to be parties who may have an interest in selected goods and services. Accordingly, resources for identifying potential buyers of medical equipment in the U.S. are compiled from subscribers of selected medical industry-specific technical publications. One such database is identified below.

<http://www.definitivedatabase.com/DataCardView.asp?TrackId=106455>

According to what is stated on the website above, the “DefinitiveDatabase” provides a resource for identifying professionals that have full decision making authority for purchasing billions of dollars of healthcare related products and services for their companies including instrumentation, computer hardware and software, medical supplies, pharmaceuticals, chemicals, laboratory equipment and services, and many more. The hundreds of selectable categories (many unavailable elsewhere) make the DefinitiveDatabase the premier resource for marketers. Included in the database are:

Job Title/Function:

Medical Doctors	61,492
Medical Directors	94,623
Family/Clinical Practice Management	44,509
Hospital Administration	1,140
Patient Admissions/Registration	16,467
Patient Accounting/Discharge	9,755
Patient Privacy, Safety & Rights	3,000
Medical Records Management	23,946
Medicare/Medicaid/HMO/PPO	6,947
Pharmacists	57,833
Pharmaceutical Management	85,499
Pharma/Genomics Management	23,224
Medical & Technical Staff Mgt	14,565
Technical Consulting/Med Research	77,108
Lab Technicians/Tech Support	42,267
Medical Research	40,721
Medical Science & Research	22,534
Biology/Biochemistry/Biotech/ Biometrics	17,423
Nursing Admin/Management	41,876
Homecare	4,644
Add'l Job Title/Functions	Inquire

**How to find U.S. import statistics?**

- [U.S. International Trade in Good and Services](http://www.census.gov/foreign-trade/Press-Release/current_press_release/press.html) (FT900) press release and supplement provides summary statistics for goods on a census and balance of payment basis and services data each month. This includes information for the most recent month and year on goods and services imports, exports and trade balances, various commodity classifications and country of origin or destination.  
[http://www.census.gov/foreign-trade/Press-Release/current\\_press\\_release/press.html](http://www.census.gov/foreign-trade/Press-Release/current_press_release/press.html)
- [USA Trade Online](http://www.census.gov/foreign-trade/reference/products/catalog/usatradeonline.html), an online subscription service, contains U.S. import statistics of commodities at the 2, 4, 6 and 10-digit Harmonized Schedule (HS) level. Monthly, year-to-date and annual statistics on value and quantity by country and customs district are provided.  
<http://www.census.gov/foreign-trade/reference/products/catalog/usatradeonline.html>

- [USA Trade CD-ROM](http://www.census.gov/foreign-trade/reference/products/catalog/usatradeonline.html) provides import statistics in compact disc (CD-ROM) format. Each disc has various data fields for HS commodities at the 2, 4, 6 and 10-digit level. Country and customs district data for value and quantity are provided on a monthly, year-to-date and annual basis.  
*<http://www.census.gov/foreign-trade/reference/products/catalog/usatradeonline.html>*
- [Import Merchandise Trade CD-ROM](http://www.census.gov/mp/www/rom/msrom8b.html) provides detailed import data on country and customs district by HS commodity code. Statistics on value, quantity, method of transportation, shipping weight, import charges and duties are provided on a monthly and year-to-date basis. A history disc, issued annually, contains four years of statistics for HS commodities.  
*<http://www.census.gov/mp/www/rom/msrom8b.html>*
- [Special Reports and Data Services](http://www.census.gov/main/www/cen2000.html) provides a multitude of export and import data products that the Census Bureau customizes in response to user requests, with payment of a nominal fee. Special products may be prepared once, periodically, or routinely.  
*<http://www.census.gov/main/www/cen2000.html>*

#### **How to find trade show information?**

Trade Show Week™ is the definitive source of information about all major trade shows. Follow this path for information on Medical and Health care Trade shows:

<http://directory.tradeshowweek.com/directory/index.asp?QUERYSET=0>

#### **How to locate agents and distributors?**

The American Importers Association offers a CD that contains a large list of US importers who are ready to buy and import many different kinds of products. These importers are looking for products to resell (retailers/wholesalers/distributors) or to use themselves (manufacturing/production).

See: <http://www.americanimporters.org/pages/exporter.html>

#### **How to locate trade and industry associations concerned with medical devices?**

Associations are a powerful resource for building and expanding networking and business opportunities, finding jobs, evaluating goods and services, and researching trends or publications. The Directory of Associations, (<http://www.marketingsource.com/associations>), is a comprehensive source of information on associations and professional societies. It provided detailed

information on business and trade associations, non-profit organizations, chambers of commerce, and other charity and community associations throughout the US.

**Information in the Directory of Associations includes the following:**

- Organization name and address - Membership statistics
- Key contact name and title - Publication and newsletter summary
- URL and E-Mail - Non-profit or For-Profit status
- Phone and fax numbers - SIC code
- Description of services and mission - Year established
- Meetings, conventions, seminars, and conference information

**Features and Benefits:**

- All data comes in comma-delimited, Access, and Excel formats, and import into virtually any application.
- Search, browse, and download the latest data using our powerful online interface.
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**CD-ROM Edition - \$749 + free unlimited online access for 1 year**

- Full database of 35,000+ entries shipped on CD-ROM
- Includes comma-delimited, Excel, and Access formats on the CD
- Unlimited use of the data within your office – no single-use limitations.
- Includes online access for 1 year, with unlimited searching and downloading.

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- View/search all 35,000+ entries and view all updated information as it is included.
- Fast, easy searching and browsing, including multiple field searching.
- All search results can be viewed online or downloaded and imported into Access, Excel, ACT!

**By-the-Slice - variable pricing**

On a tight budget? Need only a specific geography? Only looking for certain industries? Buy by-the-slice purchasing of our database! Your custom search is exported the day you order and delivered on CD-ROM in comma-delimited, Access, Excel, and printable PDF format. All custom searches are also available in print format or on mailing labels.

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