



NEWS

32nd Annual Meeting and 510(k)/OIVD Workshop Review

Over 70 people registered for the annual meeting this year, held in Rockville, Maryland on April 21-22. The meeting was a great success as determined by the post meeting evaluations. The only real problem was temperature control in the meeting room—it was either too hot or way too cold. However, by the second day of the meeting the building engineer had the environment under control.

The annual reception was well attended and offered an opportunity to sit down over a drink and discuss common problems or issues with other regulatory/quality professionals.

The 510(k)/OIVD workshop, held on the two days prior to the annual meeting was also a great success, both in terms of workshop attendance and based on post meeting attendee evaluations. The staff of the Office of In Vitro Devices Evaluation and Safety in general, and Don St. Pierre and Sousan Altaie in particular have done a great job in organizing the speakers and topics for this workshop. Over 100 people registered for the meeting. Unfortunately, too many registered at the door and as a result the room designated for the meeting was a bit crowded. We will try to get a larger room for next year's meeting. Again, there was a problem with temperature control in the room.

With respect to both meetings, the aspect most mentioned in the evaluations as an important factor in making the meetings so worthwhile for the attendees, besides the material presented, was the opportunity to speak and ask questions of the FDA presenters. Several people even acknowledged that the FDA seemed like normal people after all!

Plans are already under way for next year's annual meeting and 510(k) workshop. The dates for the annual meeting are April 20-21, 2006 and for the workshop, April 18-19, 2006. The two meetings will be held at the Double Tree Hotel in Rockville, Maryland.

Registration and Listing

Establishment Registration

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 initial establishment registration. Registration provides FDA with the location of medical device manufacturing facilities and importers. 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.

The regulation for registration can be found in 21 CFR 807.

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 (21 CFR 807.20). This includes manufacturers, contract manufacturers, contract sterilizers, specification developers,

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repackagers or relabelers, reproducers of single-use devices, remanufacturers, 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, repackage, process, or relabel a device, are no longer 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. In addition, the foreign establishments must provide FDA with the name of the United States agent representing their establishment. Foreign establishments must also continue to list the devices that they export to the U.S. on the listing form FDA-2892. 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 and phone number of their United States agent. Even if an establishment manufactures various medical devices, drugs, and/or biological products, each establishment site can designate 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.

The responsibilities of the United States agent are limited.

They include:

- 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 803), or to submit 510(k) Premarket Notifications (21 CFR 807, Subpart E).

Please note that the United States agent requirement replaces the U.S. Designated Agent (U.S.D.A.) provision in 21 CFR 807. The U.S.D.A. requirement was indefinitely stayed on July 23, 1996. In spite of being stayed, many for-

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each establishment notified FDA of the name of their U.S.D.A. and many U.S.D.A.'s registered. If a foreign establishment has previously notified FDA of the name of their U.S.D.A., this does NOT mean they have complied with the requirement to notify FDA of the name of their United States agent. ALL foreign establishments must notify FDA of their United States agent, even if it remains the person they previously identified as their U.S.D.A.

Until form FDA-2891(b) is available for reporting United States agent information, the foreign establishment must notify FDA of its United States agent by sending a letter to the address below. The letter must be signed by the establishment's official correspondent or by a senior corporate official located at the foreign establishment. The letter should include the name of a person and business name, street address, telephone and fax numbers, and email address of the United States agent. The letter must reference the foreign establishment's name, address, official correspondent, and registration number, if the establishment is currently registered. Please make sure the letter is written on the foreign establishment's letterhead. A sample letter is available. If the establishment is registering for the first time, the registration form FDA-2891 should be mailed with the United States agent notification letter. Forms FDA-2891 or FDA-2892 cannot be used to identify a United States agent.

To assist foreign establishments in locating a United States agent, CDRH has created the United States agent database. FDA provides this database as a service. FDA does not require United States agents to be listed in this database. FDA will not review the United States agent information and has no knowledge concerning the capabilities, fees, or experience of the persons representing themselves as United States agents. FDA does not endorse the use of any of the persons whose name appears in the database.

When to Register

An owner/operator of an establishment must register themselves and each establishment they own and operate within 30 days after entering into any activity requiring registration, including processing devices for exportation outside of the U.S. **If the establishment is registering for the first time, the registration form FDA-2891 must be mailed to FDA with the medical device listing form FDA-2892.** Foreign establishments must register, name a United States agent, and list their devices prior to exporting to the U.S.

How to Register

To register an establishment, form FDA-2891, "Initial Registration of Medical Device Establishment" must be completed by the owner/operator or establishment and submitted to FDA.

When registering, owner/operators should note:

- Post office (P.O.) box numbers cannot be used as addresses on the form FDA-2891. FDA will not accept P.O. box numbers for establishment and owner operator addresses. The actual street address must be used.
- In the case of small businesses, the name of the owner/operator usually is the same as the name of the registering establishment.
- The official correspondent is the person designated by the owner/operator to be responsible for:
 - the annual registration of the establishment;
 - contact with FDA for establishment registration and medical device listing issues;
 - maintenance and submission of a current list of officers and directors to FDA upon request;
 - the receipt of pertinent correspondence from FDA directed to and involving the owner/operator and/or any of the firm's establishments.
- Establishments must register within 30 days of beginning production or prior to importing or exporting a device. Preproduction status means that the establishment has not yet begun production of its device. If preproduction status is marked "Yes," FDA will not process the form or assign a registration number until the establishment sends a letter to FDA at the address below stating that the establishment will begin production within 30 days.

Form FDA-2891

Registration Form FDA - 2891

Help for completing the form can be accessed on line by double clicking on the red question mark. The definitions of operations for block 11 are reiterated below for convenience. You should select all the codes that apply to the operations performed at this location. The listed establishment type codes are defined as follows.

CONTRACT MANUFACTURER. Manufactures a finished device to another establishment's specifications. The manufacturing establishment does not commercially distribute the device under its own name.

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CONTRACT STERILIZER. Provides a sterilization service for another establishment's devices.

MANUFACTURER. Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

REMANUFACTURER. Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

REPACKAGER AND/OR RELABELER Repackager: Packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers). Relabeler: Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

INITIAL DISTRIBUTOR OR IMPORTER. Takes first title to devices imported into the United States.

SPECIFICATION DEVELOPER. Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing.

FOREIGN EXPORTER. Person who exports or offers for export to the United States, a device manufactured or processed by another person in a foreign country.

REPROCESSOR. Person who performs remanufacturing operations on a single use device.

Hard copies of FDA-2891 and FDA-2892 may be ordered in small quantities from CDRH:

FDA/CDRH
Publications (HFZ-220)
Division of Small Manufacturers, International and Consumer Assistance
Fax: 301-443-8818 Phone: 800-638-2041 (press 3) or 301-443-6597 (press 3)
Email: dsmica@cdrh.fda.gov

or

FDA/CDRH
Registration and Listing Branch
Office of Compliance
Phone: 301-827-4555 (press 3 then 1)
Email: reglist@cdrh.fda.gov

Where to Send Registration Forms

All four copies of the completed FDA-2891 and any correspondence regarding registration, including United States agent, should be mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance, HFZ-308
Regulatory Policy and Systems Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

A photocopy of the form should be made and maintained for the establishment's records.

Upon receipt of the initial registration form, CDRH will send an acknowledgement letter with the owner/operator identification (ID) number assigned to the firm. The registration form is then sent to the appropriate FDA District Office for assignment of a registration number. When the registration number is assigned, CDRH will send the official correspondent a validated copy of the FDA-2891 with the registration number. Please note that the assignment of a registration number may take between 30 and 90 days. The establishment may use the owner/operator number as proof that the registration process has been completed until a registration number is assigned.

Updating Registration Data

All registration information must be verified annually and updated if changes have occurred. FDA sends the annual registration form FDA-2891(a) to all registered firms to be verified, corrected, and returned to FDA. FDA will mail the FDA-2891(a) to the owner/operator of registered establishments automatically each year on an alphabetical schedule (21 CFR 807.21). The registration year begins January 1st and ends December 31st.

Please note that when changes occur in ownership, establishment name, official correspondent, or addresses, FDA must be notified in writing at the address above within 30 days of such changes. This notification should be a letter that identifies the registered establishment's registration and owner/operator ID numbers with a description of the changes noted above. The letter must be signed by the establishment's official correspondent.

Obtaining Establishment Registration Data from CDRH

CDRH Freedom of Information (FOI) releasable establishment registration information is available directly from the Internet without having to submit an FOI request. The data-

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base is updated monthly.

- Releasable Establishment Registration Information
- Registration Database

Frequently Asked Questions

How do I know if my registration is current?

Check the registration database on the Internet at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/registration.cfm>. The database is updated monthly.

I did not receive my annual registration form FDA-2891(a).

How do I update my establishment's registration?

FDA sends form FDA-2891(a) to registered establishments every year to update registration information. If you have lost the form, a new one will not be sent. In order to update your registration, send a letter to the address noted above stating that you would like to update and receive credit for your annual registration. Please note the establishment's registration number on the letter. The letter must be signed by the official correspondent.

I sent in the establishment registration FDA-2891 two months ago and I still have not received a reply.

Check your copy of the form FDA-2891 that you completed. If you checked Preproduction Status, your registration will not be processed until you notify FDA that you are ready to begin production. To notify FDA that you are ready to begin production, send a letter to the address noted above stating that you have begun production or will begin production within 30 days. If you have not checked this box, please call the Division of Small Manufacturers, Consumer and International Assistance at 800-638-2041 or 301-443-6597 for assistance.

My form FDA-2891 has an expiration date of December 31, 2001. Can I still use this form?

No. You must a form with a March 31, 2005 expiration date.

How much does registration cost?

There is no fee for registration.

Are foreign dental and optical laboratories required to register and list?

Yes, foreign dental and optical laboratories are not exempt from registration and listing. The exemption in 21 CFR 807.65(i) only applies to domestic establishments.

My facility only does design work. Am I required to register the facility?

Company owned design facilities must register. That is, if a manufacturer owns a manufacturing facility and a separate facility for design work, both must register. Third party design facilities are not required to register. The manufacturer that contracts out the design work is responsible for maintaining the design control documentation in accordance with 21 CFR 820.30.

I am a distributor located outside the U.S. Do I have to register?

Yes, foreign exporters must register the facility, list the devices exported to the U.S., and have a United States agent.

If I change the address of my establishment or if the owner/operator of the establishment changes, do I have to update the devices listings?

No, only the registration needs to be updated by submitting a 2891(a) form or a letter signed by the official correspondent. The changes are automatically applied to any existing listings for that owner/operator and establishment registration. You do not have to individually update the listings unless you are deleting them.

Is a U.S. Designated Agent the same as a United States agent?

No. The United States agent requirement replaces the U.S. Designated Agent (U.S.D.A.) provision in 21 CFR 807. The U.S.D.A. requirement was indefinitely stayed (placed on hold) on July 23, 1996 and has now been deleted from the regulation. The United States agent is a new requirement and different from the U.S. D.A requirement. Form FDA-2891 cannot be used to name a United States agent. A letter must be submitted to FDA with United States agent information until form FDA-2891(b) is available.

In spite of being stayed, many foreign establishment notified FDA of the name of their U.S.D.A. and many U.S.D.A.'s registered. If a foreign establishment has previously notified FDA of the name of their U.S.D.A., this does NOT mean they have complied with the requirement to notify FDA of the name of their United States agent. ALL foreign establishments must notify FDA of who their United States agent is, even if it remains the person they previously identified as their U.S.D.A.

Registration and Listing (from page 5)

Medical Device Listing

What Is Medical Device Listing

Most medical device establishments required to register with FDA must list the devices they have in commercial distribution including devices produced exclusively for export. This process is known as medical device listing and is a means of keeping FDA advised of the generic category(s) of devices an establishment is marketing. Each generic category is represented by a separate classification regulation found in Title 21 Code of Federal Regulations Parts 862-892 or FDA assigned device name. Each regulation number or device name is associated with one or more product codes. Regulation numbers with more than one product code identifies the product in further detail. For example, "Manual Surgical Instruments for General Use," 21 CFR 878.4800, contains several product codes including GAB (disposable suturing needle), GDY (scalpel), HTD (forceps) and HRQ (hemostat).

Listing of a medical device is not approval of the establishment or a device by FDA. Unless exempt, premarketing clearance is required before a device can be marketed (placed into commercial distribution) in the U.S. No listing fee is required.

Who Must List

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 list its device on form FDA-2892 within 30 days of entering the device into commercial distribution in the U.S. This includes manufacturers, repackagers and relabelers, specification developers, reproducers of single-use devices, remanufacturers, and manufacturers of accessories and components sold directly to the end user (21 CFR 807.20). Foreign manufacturers must list their devices prior to importing into the U.S. Please review the registration and listing chart under Who Must Register and List for further guidance.

When To List

An owner/operator of an establishment located in

the U.S. that is required to list should do so within 30 days of beginning a manufacturing operation as discussed above under "Who Must List." An establishment located outside of the U.S. must list the device prior to exporting to the U.S. **Please note that if an establishment is registering for the first time, both the Establishment Registration (FDA-2891) and Medical Device Listing (FDA-2892) must be submitted together. A foreign establishment also needs to submit a United States agent notification letter.**

How To List

Listing of a medical device is done by completing form FDA-2892, Medical Device Listing. FDA has developed a Product Classification Database to identify the generic category, that is, classification or device name, which is placed on form FDA-2892.

When listing, please note:

- The Product Classification Database contains classification/device names and classification numbers (product codes) to be entered on form FDA-2892. The classification name and product code identify the generic category of device for FDA. Please note that the product code (three letter code) is entered on the form, not the regulation number (21 CFR 862-892).
- Only one form FDA-2892 is required for each generic category (classification/device name/product code) of device. Therefore, for various sizes of syringes that fall within the same three letter product code, fill out only one form FDA-2892 for all of your establishments (or manufacturing sites) that manufacture this type of device.
- If the device also requires a Premarket Notification 510(k) or Premarket Approval, the product code on the form FDA-2892 should be the same as that provided on the FDA clearance or approval letter unless a new product code has been created that better represents the generic device category.
- Keep the yellow copy of the form FDA-2892 because, unlike registration, CDRH does not acknowledge receipt or return a validated copy

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of the form FDA-2892. The yellow copy of the FDA-2892 that is retained is proof of listing. The unique listing number can be found in the "Document Number" block of the form and begins with the letter A, B, C, E, Q, or R.

Forms

- Device Listing Form FDA-2892
Help for completing the form can be accessed on line by double clicking on the red question mark.
- Product Classification Database
If you cannot locate the appropriate product code from the Product Classification Database, you may contact the Division of Small Manufacturers, Consumer and International Assistance (DSMICA): phone 800-638-2041 or 301-443-6597; email dsmica@cdrh.fda.gov; fax 301-443-8818.

Obtaining Hard Copies of Forms

Forms FDA-2891 and 2892 may be ordered in small quantities from CDRH:

Publications (HFZ-220)
Division of Small Manufacturers, International
and Consumer Assistance
Fax: 301-443-8818
Phone: 800-638-2041 (press 3) or
301-443-6597 (press 3)
Email: dsmica@cdrh.fda.gov

or

Registration and Listing Branch
Office of Compliance
Phone: 301-827-4555 (press 3 then 1)
Email: reglist@cdrh.fda.gov

Where To Send Listing Forms

The completed listing forms should be mailed to:
Food and Drug Administration
Center for Devices and Radiological Health
(HFZ-308)
Office of Compliance
Regulatory Policy and Systems Branch
9200 Corporate Boulevard
Rockville, MD 20850-4015

Updating Listing Data

Unlike registration, FDA does not send out an annual update for device listing. Owner/operators and foreign establishments are responsible for keeping data on their listing forms current. Updating is accomplished through the submission of another FDA-2892 at the time the change occurs, or twice a year during June or December. Updating is required when one of the following occurs:

- A "new" device is marketed with a classification name (three letter product code) that is not currently listed. That is, establishments should list once per product code.;
- The intended use of a listed device changes in such a way that would result in its being more appropriately classified under a different generic category (classification name);
- The marketing of all models or variations of the listed device is discontinued;
- A discontinued device type, that is not listed, is re-marketed; or
- Any information that was supplied on the form FDA-2892 has changed, other than changes in proprietary and common or usual name, and changes in owner/operator information. Owner/operator changes are reported by updating the establishment's registration information. Changes in trade or brand name of the device should not be submitted.

Obtaining Medical Device Listing Data from CDRH

CDRH Freedom of Information (FOI) releasable medical device listing information is now available directly from the Internet without having to submit an FOI request.

- Releasable Medical Device Listing Information
- Listing Database

Frequently Asked Questions

My form FDA-2892 has an expiration date of December 31, 2001. Can I still use this form?

No. You must use a form with a March 31, 2005 expiration date..

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How much does device listing cost?

There is no fee for device listing.

I have only one copy of device listing form FDA-2892.

Can I photocopy this form?

No. Each form has a unique device listing number on the form. Only original forms can be used.

I submitted a device listing form FDA-2892. How can I get my device listing number?

The device listing number is entered in the "Document Number" block of the form that you submitted. It will begin with the letter A, B, C, E, Q, or R.

I am not sure if I listed my device. How can I determine if I did?

Search the device listing database on the Internet at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm>. You may search by owner/operator name, owner/operator number, or establishment registration number to find the devices that you have listed.

Should I wait to receive a registration number before I list?

No, you MUST send the registration form FDA-2891 and the device listing form FDA-2892 together if you are registering for the first time. If an establishment that is required to list submits FDA-2891 without the FDA-2892, it will be returned without processing.

I have a device listing for my product. The device has not changed. However, my company would now like to change the brand name of the product. How do I update my device listing for this change?

Do not update your device listing information for a change to the brand or trade name of the product. See "Updating Listing Data" above for when updating is required

I am an importer, can I submit the listing form FDA-2892 for the foreign establishment?

No, the foreign manufacturer must submit the form signed by the foreign establishment's official correspondent.

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FDA Approves First DNA-based Test to Detect Cystic Fibrosis

The Food and Drug Administration (FDA) today approved the first DNA-based blood test to help detect cystic fibrosis. The Tag-It Cystic Fibrosis Kit directly analyzes human DNA to find genetic variations indicative of the disease. The test will be used to help diagnose cystic fibrosis in children and to identify adults who are "carriers" of the gene variations.

"This test represents a significant advance in the application of genetic technology and paves the way for similar genetic diagnostic tests to be developed in the future," said Daniel Schultz, MD, director of FDA's Center for Devices and Radiological Health.

Cystic fibrosis is a serious genetic disorder affecting the lungs and other organs that often leads to an early death. It is the number one cause of chronic lung disease in children and young adults, as well as the most common fatal hereditary disorder affecting Caucasians in the United States. The disease affects about one in 2500-3300 Caucasian babies. Half of the people with cystic fibrosis die by the age of 30.

The Tag-It test identifies a group of variations in a gene called the "cystic fibrosis transmembrane conductance regulator" or CFTR gene that causes cystic fibrosis. FDA approved Tag-It based on a manufacturer study of hundreds of DNA samples showing that the test identifies the CFTR gene variations with a high degree of certainty. The manufacturer also provided FDA with a broad range of supporting peer-reviewed literature.

Since Tag-It detects a limited number of the more than 1300 genetic variations identified in the CFTR gene, the test should not be used alone to diagnose cystic fibrosis. Physicians should interpret test results in the context of the patient's clinical condition, ethnicity, and family history. Also, patients may need genetic counseling to help them understand their test results.

The Tag-It Cystic Fibrosis Kit is manufactured by Tm Bioscience Corporation of Toronto, Canada.

TM Bioscience, Inc. is a member of AADM.



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Who Must Register and List?

This chart gives a broad outline for foreign establishments

Operation		Register	List
1	Foreign Manufacturers (including Remanufacturers and All Foreign Establishments)	YES, 807.40(a)	YES 807.40(a)
2	Foreign Exporter of devices located in a foreign country	YES: 807.40 (a)	YES: 807.40 (a)
3	Contract Manufacturer who exports devices to U.S.	YES 807.40(a)	YES 807.40(a)
4	Contract Sterilizer who exports devices to U.S.	YES 807.40(a)	YES 807.40(a)
5	Reprocessor of Single-use Device	YES: 807.20(a)	YES: 807.20(a)
6	Manufactures a Custom Device	YES 807.20(a)(2)	YES 807.20(a)(2)
7	Relabeler or Repackager	YES: 807.20(a)(3)	YES 807.20(a)(3)
8	Kit Assembler	YES: 807.20(a)	YES: 807.20(a)
9	Device Being Investigated under IDE	NO: 812.1 (a)	NO: 812.1(a), 807.40(c)

This chart gives a broad outline for domestic establishments

Operation		Register	List
1	Contract Manufacturer who Commercially Distributes Device for Specifications Developer	YES: 807.20(a)(2),	YES 807.20(a)(2),
2	Contract Manufacturer Who does NOT Commercially Distribute Device for Specifications Developer	NO: 807.20(c)(1)	NO: 807.20(c)(1)
3	Manufacturer	YES 807.20(a)	YES 807.20(a)
4	Distribute U.S. Made Device: No Specification Initiation (Domestic Distributor)	NO: 807.20(c)(3)	NO
5	Specification Developer	YES: 807.20(a)(1)	YES: 807.20(a)(1)
6	Specification Consultant Only; No Distribution	NO	NO
7	Relabeler or Repackager	YES: 807.20(a)(3)	YES: 807.20(a)(3)
8	Kit Assembler	YES: 807.20(a)	YES: 807.20(a)

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Operation		Register	List
9	Remanufacturer	YES: 807.20(a)	YES: 807.20(a)
10	Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES: 807.20(a)(5)	YES: 807.20(a)(5)
11	Manufacturer of components and distribute only to finished device manufacturer	NO: 807.65(a)	NO
12	Contract Manufacturer of Subassembly or Component (see #12, Accessory)	NO	NO
13	Contract Packager or Labeler	NO	NO
14	Contract Sterilizer Who Commercially Distributes Device	YES: 807.20(a)(2),	YES: 807.20(a)(2),
15	Contract Sterilizer Who Does Not Commercially Distribute Device	NO: 807.20(c)(2)	NO: 807.20(c)(2)
16	Manufactures a Custom Device	YES 807.20(a)(2)	YES 807.20(a)(2)
17	U.S. Manufacturer of export only devices	YES 807.20(a)(2)	YES 807.20(a)(2)
18	Initial Distributor / Importer of Device	YES: 807.40(a)	NO: Enforcement Discretion Used for 807.22(c)
19	Device Being Investigated Under IDE	NO	NO: 807.40(c)
20	Reprocessor of Single Use Device	YES: 807.20	YES: 807.20

Definitions of Establishment Types

Contract manufacturer - Manufactures a finished device to another establishment's specifications. Foreign contract manufacturers must list. Domestic contract manufacturers that distribute devices must list.

Contract sterilizer - Provides a sterilization service for another establishment's devices. Foreign contract sterilizers must list. Domestic contract sterilizers that distribute devices must list.

Foreign Exporter – Individual, partnership, corporation or association who exports or offers for export to the United States (U.S.), a device manufactured or processed by another individual, partnership, corporation or associ-

ation in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.

Initial Distributor/Importer - Takes first title to devices imported into the U. S. An Initial Distributor must have a U.S. address.

Manufacturer - Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Remanufacturer - Any individual, partnership, corporation or association who processes, conditions, reno-

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Registration and Listing (from page 10)

vates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or in any way changes the intended use.

Repackager - Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers).

Relabeler - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

Reprocessor of Single use devices – Individual, partnership, corporation or association who performs remanufacturing operations on a single use device.

Specification Developer - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing.

U. S. manufacturer of export only devices – Individual, partnership, corporation or association who manufactures medical devices solely for export to foreign countries that are not sold in the U.S.

Further information on Registration can be found at: <http://www.fda.gov/cdrh/devadvice/341.html>

Further information on Listing can be found at: <http://www.fda.gov/cdrh/devadvice/342.html>

CDRH

Position Available

AMDM is currently seeking an individual to serve as Executive Secretary of the association. The position requires between 50 to 60 hours work per month. The position will become available January 1, 2006. The current Executive Secretary, Dr. Roger W. Johnson, is retiring from the position after 10 years.

The applicants should have experience in regulatory affairs/quality systems/clinical affairs and or the IVD industry.

Duties include but are not limited to publishing a quarterly newsletter, formatting meeting brochures, having them printed and distributing them, obtaining suitable meeting facilities for the association's annual meetings, workshops and Focus meetings, working with the administrative assistant in meeting registration, having the meeting notebooks printed, handling registration at

the meeting sites, being in contact with the meeting chairs and being in contact with the meeting speakers. Other duties include setting up association board meetings, sending out annual membership billings and following up on those who do not renew in a reasonable time, keeping the association website current, recruitment of new member companies and answering questions forwarded from the association website or from the administrative assistant.

This is a paid position.

If you are interested in this position, please send a resume to:

Association of Medical Diagnostics
Manufacturers
555 13th St., NW 7W
Washington, DC 20004-1109
202-637-5567



AMDM Events Calendar

April 18–19, 2006

AMDM/FDA 510(k)/OIVD Workshop

Double Tree Hotel • Rockville, Maryland

April 20–21 2006

AMDM 33rd Annual Meeting

Double Tree Hotel • Rockville, Maryland

September 14–15, 2006

IVD Focus XIV

San Jose area



Association of Medical diagnostics Manufacturers

555 13th Street, N.W., Suite 700

Washington, D.C. 20004-1109