Guidance for Industry and FDA Staff

Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/RegulatoryInformation/Dockets/default.htm . Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm185871.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy.

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Contains Nonbinding Recommendations

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Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The purpose of this guidance is to explain recent changes in the device registration and listing program to owner/operators and official correspondents of device establishments and to help them fulfill these new requirements.

In October 2002, section 510 of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 360) was amended by Section 207 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Pub. L. 107-250) to add a requirement for electronic submission of registration information. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (the FDAAA)(Pub. L. 110-85) further amended the device registration and listing provisions in section 510 of the Act and also added provisions to sections 737 and 738 of the Act to require certain types of device establishments to pay user fees in connection with their initial or annual registration beginning on October 1, 2007. As amended, section 510(p) of the Act requires all device establishments to submit their device registration and listing information by electronic means unless FDA grants their request for a waiver.

In addition, the FDAAA modified the timeframe for annual establishment registration and device listing to the period from October 1 through December 31 of each year.

FDA has developed an Internet-based system to facilitate the electronic submittal of registration and listing information and to provide faster access to this information for both industry and FDA. This system allows FDA to more effectively gather establishment registration information to help identify who is manufacturing medical devices and the

locations where those devices are being manufactured. Knowing where devices are being made is even more important today because having this information increases the nation's ability to prepare for, and respond effectively to, bioterrorism threats and other public health emergencies.

This guidance will explain the process for electronic registration and listing using the Internet and the processes for submitting registration user fees and for requesting waivers from the electronic submission requirements. This guidance also specifies the user fee amounts established by the FDAAA for each fiscal year (FY) through FY 2012.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOmbudsman/default.htm

Discussion

The registration and listing requirements established by the FDAAA apply to all medical device establishments who are required to register their establishments and list their devices. The next section of this guidance describes the registration and listing program that has been developed to implement these changes.

A. Registration

1. Who is required to register?

Under section 510 of the Act, domestic establishments involved in the manufacture, preparation, propagation, compounding, or processing of medical devices are required to register with the FDA. In addition, under section 510(i) of the Act, foreign establishments must register with FDA if they engage in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States. An establishment is any place of business under one management at one general physical location where a device is manufactured, assembled, or otherwise processed. 21 CFR 807.3(c).

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. 21 CFR 807.3(f).

Unless the establishment is exempt from registration (see section 510(g) of the Act and FDA's regulations at 21 CFR §§ 807.20(c) and 807.65), registration is required by the following establishment types:

- manufacturers,
- contract manufacturers and contract sterilizers if they put the device into commercial distribution,
- initial importers,
- 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 ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose.

2. How is registration information submitted?

All registration information (new, updates, or annual review) must be submitted electronically using FDA Form No. 3673 unless FDA grants you a waiver from the electronic submission requirement. Section D.1. of this document ("Electronic Submission") discusses how to submit information electronically. Section D.2. of this document discusses the procedure for requesting a waiver.

3. When did the requirement for electronic submission of registration information take effect?

Electronic submission of registration information is required by the FDAAA. The statute was signed into law on September 27, 2007, and became effective on that date for device establishments registering with FDA for the first time (i.e., initial registration), and on October 1, 2007 for device establishments completing their annual registration.

4. When is registration information to be submitted?

When an establishment registers with FDA for the first time (i.e., initial registration), it must do so within 30 days of beginning its device operations. 21 CFR 807.21. FDA recommends that updates to registration information be submitted within 30 calendar days after the change occurs. In addition, every registered establishment is required to review and update its registration on an annual basis. As a result of the FDAAA, these updates must be performed electronically during the period from October 1 through December 31 of each year. Establishments will need to review their registration each year even if they believe no changes have occurred during the previous year.

5. Are there special requirements for foreign establishments?

In addition to the initial and annual registration requirements under § 807.40, foreign establishments must submit to FDA the name, address, and telephone number for their United States agent. 21 CFR 807.40. FDA also requests that the foreign establishment provide the fax number and e-mail address for their United States agent to assist FDA in contacting these entities.

6. How are registration numbers assigned when an establishment registers for the first time?

After submission of initial registration information, FDA will notify the registrant by email of their newly-assigned registration number once the information is verified by the appropriate FDA District Office.

7. When is my registration information considered complete?

Registration information submitted by an establishment required to pay the establishment registration fee (see Section B "User Fees" below) will be considered incomplete and will not be accepted until the fee is paid, you have entered the required information electronically at our web site, and have received notification from us that all requirements have been met. See section 738(f) of the Act, as amended by section 212 of the FDAAA. FDA's notification will be sent to you via email. Until your registration is complete, including the payment of any registration fees due, your establishment will be considered to have failed to register.

8. When does my registration expire?

Previously, annual establishment registration information was collected throughout the calendar year in accordance with a schedule based on the owner/operator's name. Under the new system, the establishment registration timeframe is based on FDA's fiscal year, which runs from October 1 of one calendar year through September 30 of the next year. For example, FDA's fiscal year 2009 runs from October 1, 2008 to September 30, 2009.

As amended by section 222 of the FDAAA, sections 510(b)(2) and (i)(1)(B)(ii) of the Act now require all registrants to review and update their establishment registration information during the first quarter of each fiscal year, which is the period that runs from October 1 to December 31 of the same calendar year. This means, for example, that for fiscal year 2010, registration information must be reviewed and updated during the period beginning on October 1 through December 31, 2009

FDA will continue to consider an establishment's registration for a particular fiscal year to remain active until the final day to register for the following fiscal year. This means, for example, that if you registered for fiscal year 2009 and are re-registering for fiscal year 2010, you have until the final day of registration for fiscal year 2010 (i.e., December 31, 2009) to update your registration and, if applicable, pay your fee. During the period between October 1, 2009 and December 31, 2009, your fiscal year 2009 registration will still be considered valid.

B. User Fees

1. Is there a user fee for establishment registration?

Yes, the FDAAA established user fees for establishment registration. Beginning with fiscal year 2008, certain types of establishments were required to pay an establishment registration fee for each initial or annual registration. Those establishment types are:

- device manufacturers,
- contract sterilizers (establishments that sterilize a device for a specifications developer or any other person), if they put the device into commercial distribution,
- contract manufacturers (establishments that make a device for a specifications developer or any other person), if they put the device into commercial distribution,
- single-use device reprocessors, and
- specification developers.

2. How much is the establishment registration fee?

The establishment registration fee for fiscal year 2009 is $1,851. Congress has established a schedule of establishment registration fees for fiscal years 2008 through 2012, as shown in the table below.

FY 2008	FY 2009	FY 2010	FY2011	FY 2012
$1,706	$1,851	$2,008	$2,179	$2,364

3. Are there any reductions in fees for small businesses or other groups?

No. All establishments that are required to pay an establishment registration fee will pay the same amount.

4. When is the establishment registration fee to be paid?

You should submit the establishment registration fee before initially registering your establishment or submitting your annual establishment registration information. Instructions on how to submit the establishment registration fee are available on the CDRH Registration and Listing webpage at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. Be sure to allow for enough time for your payment to be received and recorded prior to the December 31 deadline. This process can take up to two weeks. Your registration will not be complete until FDA notifies you that all requirements have been met. FDA will send the notification to you via email, unless you received a waiver from the requirement for electronic submission, in which case we will notify you through the mail.

5. What are the consequences for failure to pay the establishment registration fee?

If you are one of the types of establishments that are required to pay an establishment registration fee, FDA will consider your registration to be incomplete and will not accept it until the fee is paid. Further, FDA may not accept submissions from you (premarket applications, premarket reports, supplements, premarket notification submissions, 30-day notices, requests for classification information, or periodic reporting concerning a class III device) until you have paid all fees owed, including all required establishment registration fees. See section 738(f)(1) of the Act, as amended by section 212 of the FDAAA.

C. Listing

1. Who is required to list?

In accordance with section 510(j) of the Act and the Agency's regulations at 21 CFR § 807.20, owner/operators who are required to register their establishments are also required to provide device listings to FDA. However, FDA currently does not require initial importers to list their devices if they did not develop the specifications for, or repackage or relabel the device. See 21 CFR § 807.22(c).

2. How is listing information to be submitted?

The new law requires you to submit all listing information (new, updates, or annual review) electronically using FDA Form No. 3673 unless FDA grants your request for a waiver from the requirement for electronic submission. Section D.1. of this document ("Electronic Submission") discusses how to submit information electronically. Section D.2. of this document discusses the procedure for requesting a waiver.

3. When is listing information to be submitted?

Owner/operators are required to submit their listing information at the time of initial registration. 21 CFR § 807.21(a). In addition, owner/operators must review and update their device listings on an annual basis. Prior to the passage of the FDAAA, these listing updates had to be performed twice each year, in June and December. However, section 223 of the FDAAA amended the timeframe for listing updates to only once each year during the period from October 1 through December 31. The new timeframe for updating device listing information coincides with the new annual registration period.

Foreign establishments who are subject to FDA's registration requirements are also required to submit device listings to FDA at the time of initial registration and to provide annual updates thereafter. With certain limited exceptions as described in 21 CFR § 807.40, a foreign establishment's device may not be imported or offered for import into the United States unless a device listing for the device has already been submitted to FDA. 21 CFR § 807.40(d).

Although listing updates are only required once each year, FDA encourages all owner/operators to update their listing information, at no additional cost, on an ongoing basis as changes occur. Examples of changes warranting an update to listing information include the following:

- another device being introduced into commercial distribution,

- a change to a previously-listed device, such as where it is being manufactured,
- a previously-listed device is removed from commercial distribution, and
- commercial distribution of a previously-discontinued device is resumed.

4. What types of listing information need to be submitted?

Owner/operators are required to submit following listing information under 21 CFR §§ 807.25 and 807.26 of the agency's regulations:

- current registration number and name of each establishment under their ownership and/or control that performs a regulated function to that device,
- the proprietary/brand name(s) under which the device is marketed,
- information concerning any regulated activities that they perform on or to the device (e.g., manufacturing),
- the FDA identification names for each device. (Identification names include the classification name and number and common or usual name), and
- labeling when they are unable to identify an appropriate FDA identification name.

Owner/operators can satisfy the identification name requirement by submitting:

- the product code for all listed devices that are exempt from pre-market notification and approval, or
- the product code for devices put into commercial distribution prior to May 28, 1976, unless the effective date for the requirement of premarket approval has been established.

In addition to the above, for each device that is not exempt from premarket notification and approval, owner/operators should include the FDA premarket submission number (510(k), PMA, PDP, HDE). The electronic system will assign a unique listing number for each device with a premarket submission number. If a device has more than one premarket submission number (for example, a device was cleared under two 510(k) numbers), a separate listing will be generated for each premarket submission number.

The electronic system will also allow you to enter multiple proprietary/brand names for a given listing where applicable.

D. Electronic Submission

As required by the FDAAA, all registration and listing information (with the exception of labeling) must be provided to FDA through the use of our electronic device registration and listing system, unless a waiver has been granted.

1. How do I submit my registration and listing information electronically?

To submit your registration and listing information electronically you need to:

1. Submit payment if you are required to do so. Instructions on how to submit the establishment registration fee are available on the CDRH Registration and Listing

webpage at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

2. Create an account and password in the FDA Uniform Registration and Listing System (FURLS). FURLS can be accessed from the CDRH Registration and Listing web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. If you have already been assigned an account ID and password, you should use that ID and password to access your information in FURLS.

3. Create sub-accounts, as necessary, for the official correspondent of each establishment that is being registered.

4. Follow the on-screen prompts to enter your establishment registration and device listing information.

5. Certify that the information is accurate and complete.

2. How do I apply for a waiver?

Section 510(p) of the Act now requires that all registration and listing information be submitted electronically unless FDA grants you a waiver "because use of electronic means is not reasonable for the person requesting such waiver." To apply for a waiver, please submit your written request with a complete explanation of why you cannot submit your registration and listing information through the Internet. Mail your request to:

Food and Drug Administration
Center for Devices and Radiological Health
Registration and Listing
10903 New Hampshire Avenue
Building 66 Room 2621
Silver Spring, MD 20993-0002

FDA does not anticipate there will be many instances in which electronic submission of registration and listing information will not be reasonable for the person requesting the waiver. Please note, however, that if you are granted a waiver, you will still be responsible for submitting the registration fee if your establishment type is required to pay a fee. Waivers are not indefinite in term and need to be renewed annually. A request for a waiver from electronic registration and listing must be submitted to FDA for each fiscal year. You should provide adequate time before the December 31 deadline for FDA to review your request and determine whether a waiver will be granted.

3. What do I do if I need help submitting my information electronically?

Online help will be available for each step during the electronic registration and listing process. If you need additional assistance, you may contact the Division of Risk Management Operations, Regulatory Policy and Systems Branch at:

Email: reglist@cdrh.fda.gov
Phone: 301-796-7400

Or

You may also contact the Division of Small Manufacturers, International, and Consumer Assistance at:

Email: dsmica@cdrh.fda.gov
Phone: 301-796-7100 or 800-638-2041

E. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0625 (expires 03/31/2012).