

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 807

[Docket No. FDA-2009-N-0114]

RIN 0910-AF88

### Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration is proposing to amend its regulations governing medical device establishment registration and device listing. The proposed revisions would modify FDA's current regulations at part 807 (21 CFR part 807) to reflect recent statutory amendments to the device registration and listing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Food and Drug Administration Amendments Act of 2007 (FDAAA), which was enacted on September 27, 2007, amended section 510 of the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms, and also specified the timeframes when establishments are required to submit such information. In accordance with FDAAA, the agency launched FDA's Unified Registration and Listing System (FURLS), and Internet-based registration and listing system. FDAAA requires electronic submission of device registration and listing information unless FDA grants a waiver request.

In addition, this proposal would facilitate FDA's collection of additional registration information from foreign establishments as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). It also would update certain provisions in part 807 to improve the quality of registration and listing information available to FDA. FDA relies on having complete and accurate registration and listing information in order to accomplish a number of important public health objectives.

**DATES:** Submit written or electronic comments on the proposed rule by June 24, 2010. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by April 26, 2010, (see the "Paperwork Reduction Act of 1995" section of this document). See sections IX and X of this document for the proposed effective and proposed compliance dates of a final rule based on this document.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2009-N-0114 and RIN number 0910-AF88, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) at FAX: 202-395-7285, or e-mail comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Please mark your comments to the attention of the FDA desk officer and reference this rule.

#### Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

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#### I. Background

We originally published establishment registration regulations for medical devices in the **Federal Register** of September 3, 1976 (41 FR 37458) (proposed rule) and August 23, 1977 (42 FR 42520) (final rule), and device listing regulations in the **Federal Register** of September 30, 1977 (42 FR 52808) (proposed rule), and August 25, 1978 (43 FR 37990) (final rule).

These regulations called for establishment registration and device listing information to be submitted to the Center for Devices and Radiological Health (CDRH) on several paper forms: FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing. Once these forms were completed and submitted to FDA, FDA then forwarded them to a data entry contractor who entered the information into FDA's device registration and listing database.

In June 2002, section 321 of the Bioterrorism Act amended section 510(i) of the FD&C Act to require those foreign

establishments who are required to register with FDA to do so by electronic means, and to include additional information identifying certain parties involved in the importation of the foreign establishment's devices into the United States as part of their registration. Subsequently, in October 2002, section 207 of MDUFMA further amended section 510 of the FD&C Act by extending the requirement for electronic submission of registration information to include domestic firms as well as foreign firms. However, when adding these new electronic submission requirements, which appear in section 510(p) of the FD&C Act, Congress chose to delay their implementation so that FDA would have an opportunity to first put systems in place to accommodate the electronic receipt of registration information. This was accomplished by including a requirement in section 510(p) of the FD&C Act for the Secretary of the Department of Health and Human Services (the Secretary) to make a finding that the electronic receipt of registration information was feasible before implementing electronic registration.

As reflected in FDAAA, the most recent legislation establishing changes to FDA's device registration and listing program, FDA has now developed a system that makes the electronic receipt of device registration and listing information feasible. FDAAA amended section 510(p) of the FD&C Act by eliminating the need for a feasibility finding and requiring both establishment registration and device listing information to be submitted using electronic means unless FDA grants a waiver request. In accordance with FDAAA, FDA's Unified Registration and Listing System (FURLS), which is a new Internet-based system, became operational on October 1, 2007. FDA believes this electronic system will ultimately make the process of submitting registration and listing information more efficient for industry and will provide faster access to this information for both FDA and industry.

In addition, the new electronic system will allow FDA to more effectively gather information concerning marketed devices. We rely on having complete and accurate registration and listing information to accomplish a number of important statutory and regulatory objectives. For example, we use registration and listing information to:

- Identify establishments producing marketed medical devices;
- Identify establishments producing a specific device when that device is in short supply or is needed for a national emergency. This information helps us

facilitate prompt shipment of devices to the places where they are needed most. For example, during a bioterrorism incident, we could use device listing information to identify establishments that could be helpful in preventing or counteracting the deadly effects of biological weapons; with this information, we could facilitate prompt shipment of the devices as needed;

- Facilitate the recall of devices marketed by owners or operators of device establishments;
- Identify and catalogue marketed devices;
- Administer our postmarketing surveillance programs for devices;
- Identify devices marketed in violation of the law;
- Identify and control devices imported or offered for import into the country from foreign establishments; and
- Schedule and plan inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

We also rely on registration and listing information to help us comply with several other statutory provisions. For example, we use this information to generate accurate estimates of the number of businesses that are affected by our rulemaking activities. These estimates help us assess the impact of our regulations on regulated industry, which we are required to do under the Regulatory Flexibility Act of 1980 (Public Law 96–354) (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Public Law 104–121); the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) (2 U.S.C. 1501 *et seq.*); the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520); Executive Order 12866 (September 30, 1993); and the Congressional Review Act (section 251 of Public Law 104–121).

Registration and listing information will continue to be used for all of the important public health purposes outlined previously. The electronic submission of registration and listing information allows us to use such information more quickly and effectively to carry out all of the activities described previously.

In addition, electronic submission of registration and listing information furthers the purpose of the Government Paperwork Elimination Act of 1998 (Public Law 105–277, Title XVII) (GPEA). GPEA requires Federal agencies to give persons who are required to maintain, submit, or disclose information, the option of doing so electronically when practicable as a substitute for paper, and to use

electronic authentication (electronic signature) methods to verify the identity of the sender and the integrity of the electronic content. We believe that electronic submission of registration and listing information furthers the purpose of this law and makes the registration and listing processes more efficient and effective both for industry and us.

## II. Summary of Current Registration and Listing Requirements

### A. Summary of Section 510 of the FD&C Act (21 U.S.C. 360)

Section 510 of the FD&C Act contains the statutory requirements pertaining to device registration and listing. Section 510(b), (c), and (d) of the FD&C Act address registration obligations that apply to domestic establishments. Section 510(c) of the FD&C Act includes the requirement for owners or operators to immediately register their establishment “upon first engaging in the manufacture, preparation, propagation, compounding, or processing of \* \* \* device or devices.” As clarified in section 510(a)(1) of the FD&C Act, the term “manufacture, preparation, propagation, compounding, or processing” as used in section 510 is intended to be rather broad and also includes “repackaging or otherwise changing the container, wrapper, or labeling of any \* \* \* device package in furtherance of the distribution of the \* \* \* device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.”

In addition to the initial registration requirement in section 510(c), owners or operators of domestic device establishments are also required to renew their registrations on an annual basis. Prior to FDAAA, section 510(b) provided that such registration had to be completed “[o]n or before December 31 of each year.” FDAAA amended the timeframes in section 510(b) and now requires annual registration to be performed during the 3-month period beginning on October 1 and ending on December 31 of each year.

Section 510(d) of the FD&C Act requires an owner or operator that has previously registered an establishment to immediately update his registration information on file with the agency to include any additional establishment that he owns or operates in which he begins the “manufacture, preparation, propagation, compounding, or processing” of a device or devices.

Section 510(i) of the FD&C Act contains certain registration and listing requirements that specifically pertain to

foreign establishments. The owner or operator of a foreign establishment has to register and list with FDA if the establishment is engaged in the “manufacture, preparation, propagation, compounding, or processing of \* \* \* a device that is imported or offered for import into the United States.” Section 510(i) specifies that the registration and listing information must be submitted to FDA by electronic means, and also requires the foreign establishments to furnish, as part of their registration, “the name of each importer of [the establishment’s] device in the United States that is known to the establishment, and the name of each person who imports or offers for import such \* \* \* device to the United States for purposes of importation.” Prior to the passage of FDAAA, section 510(i) required foreign establishments to complete their annual registration “[o]n or before December 31 of each year.” FDAAA amended the timeframes in section 510(i) and now requires annual registration to be performed during the 3-month period beginning on October 1 and ending on December 31 of each year.

Section 510(g) of the FD&C Act establishes specific exemptions from registration requirements and permits the Secretary, under section 510(g)(5), to create additional exemptions by regulation where the Secretary finds that registration by those persons is not necessary for the protection of public health.

Under section 510(e) of the FD&C Act, we may assign a registration number to any person or establishment who registers. We may also prescribe a uniform system for the identification of devices intended for human use and require that persons who are required to list their devices do so in accordance with such a system.

Section 510(f) of the FD&C Act is the provision governing the public availability of registration and listing information that has been submitted to FDA in accordance with section 510.

Section 510(j) of the FD&C Act prescribes the requirements for device listing. Section 510(j)(1) requires every person who registers to file, at the time of registration, a list of all devices that are being “manufactured, prepared, propagated, compounded, or processed by him for commercial distribution” and which have not been previously listed by him or her. Section 510(j)(1) further requires that the listing information be prepared and submitted in the “form and manner prescribed by the Secretary.” Section 510(j)(2) of the FD&C Act requires registrants to periodically update their listing information. Prior to

the passage of FDAAA, registrants were required to update their device listings two times each year, once in June and once in December. As amended by FDAAA, section 510(j)(2) now requires device listing information to be updated only once each year during the period beginning on October 1 and ending on December 31, which is the same 3-month period during which establishments are required to complete their annual registration.

Section 510(p) of the FD&C Act, as amended by FDAAA, requires the electronic submission of device registration and listing information unless the Secretary grants a request for a waiver because use of electronic means is not reasonable for the person requesting the waiver.

On October 8, 2009, FDA published the document “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.” The purpose of the Guidance is to explain changes in the device registration and listing program that are required by Section 207 of the Medical Device User Fee and Modernization Act of 2002 and the Food and Drug Administration Amendments Act of 2007. Copies of the guidance can be found on the Internet at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm185871.htm>.

## *B. Summary of Current Registration and Listing Regulations*

### *1. Who Must Register and List Under the Current Regulations?*

Under current part 807 (21 CFR part 807) of FDA’s regulations, with certain exceptions, owners or operators of establishments that engage in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use must, in addition to other requirements, register their establishments and submit listing information for each of their devices in commercial distribution. FDA has interpreted the types of establishments that must register and/or list to include, among others, manufacturers, contract manufacturers and contract sterilizers (currently required to register and list only if they also distribute the device commercially on behalf of the party initiating the specifications), specification developers, remanufacturers, repackagers, re labelers, single-use device (SUD) preprocessors, and initial importers (these parties are currently required to register but need

not submit listing information). Foreign device establishments that manufacture, prepare, propagate, compound, process or export a device that is imported or offered for import into the United States also must comply with the registration and listing requirements, including the requirement to identify a U.S. agent. The current regulations provide for all registration and listing information to be submitted to us using paper forms FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing, as required by § 807.22.

### *2. What Are the Registration Requirements Under the Current Regulations?*

The existing regulations in part 807 contain various provisions governing the requirements for registration. Among others, those provisions include the following:

- Section 807.21(a) requires owners or operators of establishments entering into the manufacture, preparation, propagation, compounding, assembly, or processing of a device or devices to register their establishment within 30 days after beginning such an activity at their establishment.
- Sections 807.25 and 807.40 describe the information required to be submitted by owners or operators of domestic and foreign establishments as part of their registration. This information includes:
  - The names of the registered establishment, its owner or operator, and its official correspondent;
  - Contact information for the official correspondent;
  - Trade names used by the establishment;
  - The types of operations or activities conducted at the establishment; and
  - The name and contact information for their designated U.S. agent (applies only to foreign establishments).
- Section 807.21(a) requires owners or operators to renew their establishment’s registration on an annual basis in accordance with a schedule specified in the regulations.
- Section 807.35 provides for FDA to assign a permanent registration number to each establishment after reviewing the information provided to us on Form FDA 2891 at the time of the establishment’s initial registration.

### *3. What Are the Listing Requirements Under the Current Regulations?*

The listing provisions currently found in part 807 include, among others, the following:

- Owners or operators of establishments must, at the time of registration, submit a list of devices being manufactured or processed at the establishment that are in commercial distribution at that time using forms FDA 2892 (§ 807.21(a)).

- The device listing information required to be submitted to us under § 807.25(f) includes, but is not limited to the classification name and number for the device (in practice, the product code assigned to the device by FDA is ordinarily provided rather than the classification name and number); the proprietary and common names associated with the device; the name and FDA-assigned identification number of the owner or operator; the name, registration number, and establishment type of all establishments under the joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or re labeled; the number assigned by FDA to an approved application for each device listed that is subject to pre market review under section 505 of the FD&C Act (21 U.S.C. 355) or section 515 of the FD&C Act (21 U.S.C. 360e) (in practice, the owners and operators are also providing 510(k) clearance and Humanitarian Device Exemption (HDE) numbers); the reason for the submission (e.g., represents a new device listing, an update to an existing listing, or the device is being discontinued); and if the listing relates to a previously listed device, as in the case of an update, the initial listing number for the device.

- The current regulations at § 807.30(b) require owners or operators to update their device listing information twice each year during June and December, or at their discretion, at the time the change occurs. Updated information must include, but need not be limited to:

- A list of each device introduced by the registrant for commercial distribution that has not been included in any previously-submitted list;

- All previously-listed devices for which commercial distribution has been discontinued;

- A list of all devices for which a notice of discontinuance was submitted and for which commercial distribution has since that time been resumed; and

- Information about any other material change to listed products, as required under current § 807.30(b).

#### 4. Who Is Not Covered by Registration and Listing Requirements Under the Current Regulation?

Under the current regulations, certain establishments are exempt from the registration and listing requirements set

forth in part 807. Section 510(g) of the FD&C Act, which establishes certain exemptions from registration requirements, authorized FDA to exempt additional classes of persons from registration requirements by regulation when we determine that registration by those persons is not necessary for the protection of the public health. (21 U.S.C. 360(g)). These exemptions are reflected in our regulations at § 807.65. Section 807.65 provides an exemption from registration requirements for the following types of establishments:

- A manufacturer of raw materials or components;
- A manufacturer of veterinary devices;
- A manufacturer of common and widely-used laboratory equipment and/or chemical reagents not labeled or promoted for medical use; and
- Carriers whose business it is to transport and deliver devices.

Section 807.65 further exempts from registration requirements the following types of establishments, provided they are domestic establishments:

- Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their professional practice;
- Persons who manufacture, prepare, propagate, compound or process devices solely for use in research, teaching, or analysis, and do not introduce such devices into commercial distribution;
- Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user; and
- Persons who dispense previously-manufactured devices or render services to the ultimate consumer (i.e., patient, physician, layman, etc.), such as a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, as well as personnel from a hospital, clinic, dental laboratory, orthopedic or prosthetic retail facility whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

Additionally, under current § 807.20(c), establishment registration and device listing requirements do not apply to any person who:

- Manufactures the device for another party who initiated the specifications and distributes the device;
- Sterilizes the device on a contract basis for another party who distributes the device; or
- Acts only as a wholesale distributor and does not manufacture, repackage, process, or re label the device.

#### 5. Do the Current Regulations Permit the Disclosure of Registration and Listing Information?

Section 807.37 of the current regulations addresses the extent to which registration and listing information submitted to us will be available for public disclosure and the procedure for obtaining access to such information. Specifically, that provision states that all registration information submitted by an establishment on forms FDA 2891 and FDA 2891a will be made available for inspection at the CDRH Office of Compliance in Maryland and also at the district office that has responsibility for that establishment. In practice, these documents are no longer kept at the district offices, but can still be requested from the Office of Compliance. Registration data also can be searched and downloaded from CDRH's Web site at [www.fda.gov/cdrh](http://www.fda.gov/cdrh).

Device listing information submitted on Form FDA 2892 may also be requested as specified in current § 807.37(b). Listing information can also be searched and downloaded from CDRH's Web site. The search and download capabilities of the Web-based database is the method of obtaining registration and listing data that is most often used by the public.

#### III. Highlights of the Proposed Changes to the Current Registration and Listing Requirements

This proposal would modify the current registration and listing regulations to reflect FDAAA's mandate that device registration and listing be submitted electronically and to facilitate the government's collection of additional registration information as mandated by the Bioterrorism Act. It also would revise certain registration and listing provisions to improve the quality of registration and listing information that will be available to FDA for use in pursuing its important health objectives.

##### *Proposed Changes to the Current Registration and Listing Regulations*

We are proposing the following changes to the current registration and listing regulations:

##### 1. Switch to an Electronic Registration and Listing System

The current regulations in part 807 require owners and operators of device establishments to submit their registration and listing information to FDA using paper forms (Forms FDA 2891, FDA 2891a, and FDA 2892). This proposal would update the regulations to conform to the requirement in section 510(p) of the FD&C Act, as amended by

FDAAA, that such information be provided to FDA electronically unless FDA grants a request for a waiver.

As part of the new electronic registration and listing system, each owner or operator establish an account using the FURLS, from which the owner or operator creates and updates his or her establishment registration and device listing information. Information submitted to FDA prior to September 15, 2007, has already been migrated to the new electronic database and thus there is no need for owners or operators to reenter this information.

In accordance with section 510 of the FD&C Act, as amended by sections 222 through 224 of FDAAA, device establishment owners and operators have been using FURLS to submit their establishment registration and device listing information electronically since the system became operational on October 1, 2007. In addition, in accordance with section 510(p), as amended by FDAAA section 224, FDA is granting waivers from the new electronic submission requirements only to those owners or operators for whom electronic registration and listing is not reasonable.

## 2. Foreign Establishment Registration and Listing Requirements of the Bioterrorism Act

Before its devices will be allowed into the United States, each foreign establishment that is required to register must supply to FDA the registration information required by part 807, including the name and contact information for its U.S. agent. Section 321 of the Bioterrorism Act affected foreign establishment registration in part by amending section 510(i) of the FD&C Act to require, as part of an establishment's registration, the name of each importer of the device that is known to the establishment and the name of each person who imports or offers to import the device into the United States. This proposal would amend part 807 to reflect in our regulations the Bioterrorism Act requirement that foreign establishments whose devices are imported or offered for import into the United States must identify: (1) All importers known to the foreign establishment and (2) the name of each person who imports or offers to import the foreign establishment's device into the United States. Proposed changes to § 807.3 also would add specific definitions for these two new categories of information that need to be submitted by foreign establishments.

On August 29, 2006, FDA issued a proposed rule (71 FR 51276) relating to drugs (including certain blood products)

which proposed to revoke exemptions from registration and listing requirements found in §§ 207.40(a) and 607.40(a) (21 CFR 207.40(a) and 607.40(a)) relating to foreign establishments whose drug products enter a foreign trade zone and are then re-exported from the foreign trade zone without having entered U.S. commerce. The same rule also proposed to revoke exemptions in §§ 207.40(b) and 607.40(b) which allow a component of a drug imported under section 801(d)(3) of the FD&C Act (or a blood product imported under section 801(d)(4) of the FD&C Act) to be imported or offered for import into the United States even if the component is not listed and manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. (21 U.S.C. 381(d)(3) and (d)(4)).

Consistent with the revisions proposed to §§ 207.40 and 607.40, and for the reasons discussed in that rule (see 71 FR 51283–51284 and 51324), we are proposing to eliminate the exemption in § 807.40(a) for foreign establishments whose devices enter a foreign trade zone and are re-exported from the foreign trade zone without entering U.S. commerce, and the exemption in § 807.40(c) for devices that are imported under section 801(d)(3) of the FD&C Act (21 U.S.C. 381(d)(3)). We believe that removing the exemptions from registration and listing requirements for devices entering foreign trade zones and for products imported under section 801(d)(3) of the Act is consistent with Congress' desire, as reflected in the Bioterrorism Act, to increase the Nation's ability to prepare for and effectively respond to bioterrorism and other public health emergencies by requiring foreign establishments to provide more, rather than less, information for imported products.

## 3. Change in Requirements Relating to Contract Manufacturers and Sterilizers

The proposed regulation would amend current part 807 regarding the applicability of registration and listing requirements to contract manufacturers and contract sterilizers. Under the proposed regulation, all contract manufacturers and sterilizers would be required to register their establishment and list their devices. Currently § 807.20(a)(2) states that contract manufacturers who do not put the device into commercial distribution do not have to list those devices. In addition, § 807.20(c)(1) and (c)(2) currently provide that contract manufacturers and sterilizers who do not put a device into commercial

distribution do not have to register or list. These two provisions, taken together, have been interpreted as requiring contract manufacturers and sterilizers to register and list only if they distribute the device commercially on behalf of the person initiating the specifications.

FDA relies on having a complete and accurate registration of device establishments and the devices processed at those establishments in order to accomplish a number of important statutory and regulatory objectives. FDA's recent experience with contract manufacturers and contract sterilizers since October 1, 2007, suggests that many of these firms that have voluntarily registered and listed in the past, no longer do so. When such establishments experience a problem, it can have significant impact on the product lines for the one or multiple firms for which it is contracted to provide manufacturing or sterilization services. Knowing which products are manufactured or sterilized at the affected site could facilitate the recall of the impacted devices. FDA also believes that knowing that these manufacturing sites exist would be critical information when a device is in short supply or needed in the event of a national emergency.

We are proposing to modify § 807.20(a)(2) and delete § 807.20(c)(1) and (c)(2) such that all contract manufacturers and contract sterilizers would be required to register their establishments and list their devices regardless of whether they put the device in commercial distribution.

## 4. Requiring Submission of the FDA Product Code Assigned to a Device Rather Than the Classification Name and Number

Current § 807.25(f)(1) indicates that when listing their devices, registrants need to provide, among other information, the classification name and number of each device. The new electronic system would require exempt devices to be identified by product code rather than by classification name and number. The product code is already requested for such devices. This change to the regulation, therefore, is intended to codify the existing practice.

## 5. Requiring Submission of the 510(k) or HDE Number for Non-Exempt Device Listings

Current § 807.25(f)(3) requires owners or operators to provide as part of their device listing information the premarket submission number assigned by FDA under section 505 or 515 of the FD&C Act (21 U.S.C. 360j) for approved

devices. FDA also has been requesting owners or operators to identify as part of their device listing information the assigned premarket notification number for a device cleared under section 510(k) of the FD&C Act (i.e., the 510(k) number) or the assigned HDE number for a device approved for marketing under section 520(m) of the FD&C Act. This proposal amends § 807.25(f)(3) (at proposed § 807.25(g)(4)) to include 510(k) numbers and HDE numbers among the types of premarket submission numbers required to be provided as part of the listing information submitted to FDA for non-exempt devices.

Collection of the premarket submission numbers allows FDA to better protect the public health by providing a mechanism FDA can use to follow the total product life cycle of non-exempt medical devices. Having access to this information through the listing process also facilitates the agency's use of information that was collected during premarket review to identify devices by attributes other than the product code that is assigned to the product. This would include information such as whether the device contains materials from animal sources, is an implanted device, and other information that generally is not collected as part of the device listing.

Until FDA began collecting the 510(k) number, it was difficult to determine which products listed under registration and listing requirements were being marketed under a specific premarket notification clearance. At times, the product code assigned to a device during the premarket notification clearance process was not accurately identified when the device was listed. This meant that a device assigned one product code during the 510(k) review process could ultimately be listed with FDA under a different product code once the device was put in commercial distribution.

This lack of a direct link between products on the market and their premarket filings made it difficult for FDA to know which devices that we had cleared were being marketed, and where the devices were being marketed. This change would allow us to better identify, evaluate, and resolve potential problems with marketed devices when public health concerns arise.

Proposed § 807.25(g)(4) would codify the practice of including the 510(k) number when listing a medical device that has gone through premarket clearance or the approved HDE number in the electronic device registration and listing system. This change also would provide FDA with a tool to help ensure

that devices that lack a required premarket clearance or premarket approval are not marketed.

#### 6. Identification of a Contact Person to Administer the Electronic System Accounts

Prior to the implementation of FURLS, each owner or operator identified an official correspondent on Forms FDA 2891 and FDA 2891a. The official correspondent was the only person who could supply, delete or change information related to a device establishment and its listings. As a result of the passage of FDAAA, FDA began collecting device registration and listing information using FURLS beginning in October 2007. When using FURLS, an owner or operator needs to identify not only an official correspondent for the establishment but also a contact person for the owner or operator. The contact person is the only person who can administer the owner or operator's user accounts in FURLS.

In instances where owners or operators have only one establishment, they may choose the same person to serve as both the contact person for the user account and the official correspondent for the establishment. For owners or operators with multiple establishments, the contact person for the owner or operator may also serve as the official correspondent for any or all of the owner or operator's establishments. Alternatively, using the accounts management software for FURLS, the owner or operator may create subaccounts in which different official correspondents are identified for each establishment.

Proper control of access to accounts and control of the ability to update an establishment's online information is necessary to avoid errors. Therefore, we are proposing that each owner or operator identify only one contact person within the owner or operator's organization who will be responsible for creating the master account in FURLS for the owner or operator and assigning subaccounts to each establishment, if needed. Once the contact person creates the master account and any needed subaccounts, the official correspondent can then use the accounts to submit the owner or operator's establishment registration and device listing information to FDA.

#### 7. Establishment Operations Will Be Reported Through Device Listing

Currently, owners or operators are required to identify the operations or activities that they conduct at their establishments as part of the registration information required on Forms FDA

2891 and FDA 2891a and also as part of the listing information required on Form FDA 2892. Under the proposed rule, we would require owners or operators to identify the operations or activities their establishments engage in only as part of their device listings. This is because the new electronic system has been designed to automatically migrate the information provided in the device listing to the owner or operator's registration, thus saving the owner or operator from having to provide the same information twice. Because under the new system owners or operators would only have to supply such information once, this change will save time and help avoid inconsistencies between the registration and listing information for a single establishment.

#### 8. Registration Fees

FDAAA section 212 requires that certain medical device establishments pay a registration user fee when they initially register with us and for each annual registration thereafter. Therefore, we are deleting the sentence at the beginning of § 807.20(b) that states, "No registration or listing fee is required."

#### 9. Definition of Restricted Devices

This proposal also would revise the definition of "restricted device" in § 807.3(i) to more accurately reflect the provisions of the FD&C Act that provide us with authority to restrict devices.

### IV. Description of the Proposed Rule

We are proposing to amend our establishment registration and device listing regulations in part 807 in order to implement changes that are required by FDAAA, section 321 of the Bioterrorism Act, and section 207 of MDUFMA.

As a result, in this proposal we have revised and re-codified some provisions, added new provisions, and eliminated others. The following discussion of the proposed rule describes the new provisions we would add to part 807 and also the changes we would make to the existing provisions.

#### A. General

##### 1. What Is the Purpose of the Proposed Changes to Part 807?

Changes we are proposing to the current registration and listing requirements are intended to:

- Improve the accuracy and availability of postmarket medical device information;
- Make submission of the information required by the registration and listing provisions of part 807 easier and faster;
- Comply with the Bioterrorism Act and MDUFMA by implementing an

electronic registration and listing system;

- Comply with the additional information collection requirements of the Bioterrorism Act;
- Eliminate ambiguity and clarify requirements in the current device registration and listing regulations; and
- Link postmarket listing data collection with related premarket data by collecting premarket review numbers assigned by FDA.

## 2. Who Would Be Affected by the Proposed Changes to Part 807?

The proposed changes to part 807 would impact all device establishments that are required to register their establishments and list their devices with FDA; however, the revised regulation would have the greatest impact on contract manufacturers, contract sterilizers, and foreign establishments.

a. *Contract manufacturers and sterilizers.* The proposed rule would require that all contract manufacturers and contract sterilizers register their establishments and list their devices. Currently, there are two provisions, § 807.20(a)(2) and (c), that address the registration and listing requirements for contract manufacturers and contract sterilizers. Current § 807.20(a)(2) states: “\* \* \* person who only manufactures devices according to another person’s specifications, for commercial distribution by the person initiating specifications, is not required to list those devices.” Current § 807.20(c) states: “Registration and listing requirements shall not pertain to any person who: (1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device; (2) sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices. \* \* \*”

These two provisions, taken together have been interpreted to require registration and listing by contract manufacturers or contract sterilizers only when they are the party placing the device into commercial distribution. We are proposing to delete current § 807.20(c)(1) and (c)(2) and, in addition, would revise § 807.20(a)(2) in a manner consistent with section 737(13)(A) of the FD&C Act (21 U.S.C. 379i(13)(A)), a provision added by FDAAA that addresses which types of establishments are subject to device registration user fees. These changes to § 807.20(a) and (c) will have the effect of requiring all contract manufacturers and sterilizers to register and list regardless of whether they commercially distribute the devices. The agency

believes this approach to registration and listing for these devices and combination products best enables effective oversight by appropriate agency components. Having all contract manufacturers and sterilizers register and list would provide us with basic information about the entities that make and clean devices. This information would allow us to respond in a more timely and effective fashion in the case of an adverse event, shortage, or other problem associated with one of these establishments. The information would also assist us in our fundamental regulatory activities, such as planning and scheduling inspections.

We recognize that with regard to combination products, this approach to registration and listing may result in registration of the same facility and listing of the same product with more than one agency component. However, we also note the agency is currently working to develop harmonized electronic registration and listing systems within FDA. We anticipate that once these harmonized systems are in place, the agency will be able to implement a more streamlined approach to facility registration and product listing for combination products.

(b) Foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States are currently required to register and to submit listing information in accordance with section 510 of the FD&C Act and § 807.40 of our regulations. These foreign establishments are also required to designate a U.S. agent, and to provide contact information for that person to FDA.

The revised regulation will codify requirements established by section 222 of FDAAA, which changed the timeframes in section 510(i) of the FD&C Act for annual registration by foreign device establishments to a specific 3-month period each year beginning on October 1 and ending on December 31. It also would codify in part 807 certain requirements established by section 321 of the Bioterrorism Act. The Bioterrorism Act amended section 510(i) of the FD&C Act to require those foreign establishments that have to register with FDA to do so by electronic means, and to include additional pieces of information as part of their registration. The additional information required by section 510(i) includes the name of each “importer of such \* \* \* device in the United States that is known to the establishment,” and the name of each “person who imports or offers for import

such \* \* \* device to the United States for purposes of importation.” As discussed at section IV.A.4 of this document, this proposal also would incorporate, at § 807.3, definitions clarifying these two new categories of information that need to be submitted by foreign establishments.

Most of the provisions in section 321 of the Bioterrorism Act became effective on December 8, 2002, but the effective date of the electronic registration requirement was later delayed by MDUFMA section 207 (which added section 510(p) of the FD&C Act) so that FDA would have an opportunity to put systems in place to accommodate the electronic receipt of registration information. The agency has now developed a system, FURLS, which became operational on October 1, 2007, that makes the electronic receipt of device establishment registration and device listing information feasible.

## 3. Who Would Be Exempt From Registration and Listing?

We propose no changes to the categories of persons or establishments that are exempt from registration requirements under § 807.65. As discussed in section IV.A.2.a. of this document, however, we are proposing to eliminate the exemption from listing requirements for contract manufacturers under § 807.20(a), and the exemption from registration and listing requirements for contract manufacturers and contract sterilizers under § 807.20(c)(1) and (c)(2). As a result, all contract manufacturers and sterilizers would need to register and list regardless of whether they put the devices into commercial distribution.

For the same reasons as stated in the proposed revisions to part 207 of FDA’s regulations addressing drug establishment registration and listing, which were published in the **Federal Register** of August 29, 2006 (71 FR 51276), we are proposing to revoke exemptions in current § 807.40(a) relating to foreign establishments whose devices enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U.S. commerce, and in § 807.40(c) regarding devices that are imported into the United States under section 801(d)(3) of the FD&C Act for further processing and then exported without having been placed on the U.S. market. We propose eliminating these two exemptions because of certain statutory changes that have occurred since the publication of the final rule on foreign establishment registration and listing. Those changes include enactment of the Bioterrorism Act, which reflects Congress’ desire to



increase the nation's ability to prepare for and respond effectively to bioterrorism and other public health emergencies and Congressional findings that greater controls over imported products be part of that effort.

#### 4. What Definitions and Interpretations of Terms Would Apply to Part 807?

In proposed § 807.3, we set forth new definitions and interpretations of terms as follows:

a. We are proposing to add a definition for the term Product Code at § 807.3(k) to help describe the identifying information that would have to be submitted when listing a medical device that is exempt from premarket notification requirements. Currently, the product code is a three-letter code used by FDA to identify the generic category of a device. Section 807.25(f)(1) of our regulations currently states that the owner or operator must identify the classification name and number when providing device listing information. In practice, however, CDRH instead has requested and accepted the three-letter product code which can be identified from the Web-based medical device classification database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

b. Proposed § 807.3(v) includes a definition for FURLS, which as stated previously, stands for FDA Unified Registration and Listing System. FURLS is the Internet-based electronic system that owners and operators of device establishments must use to submit device registration and listing information to FDA.

c. As described more fully in section IV.B.3 of this document, this proposal would help to implement the requirement in section 510(i) of the FD&C Act, as amended by the Bioterrorism Act, that a foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States provide as part of its registration with FDA identifying information for each importer of such device that is known to the establishment. In proposed § 807.3(x), we are proposing to define the term "importer" to mean a company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's device that is imported into the United States. We recognize that a foreign establishment may have more than one "importer" and we are proposing to include in this term any owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's

device that is imported into the United States. Under this proposal, the term "importer" would not include the consumer or patient who ultimately purchases, receives, or is the end user of the device, unless the foreign establishment ships the device directly to the consumer or patient. We invite comments on our definition of importer, including the scope of the entities included in the definition.

d. Section 510(i) of the FD&C Act, as amended by the Bioterrorism Act, also requires that foreign establishments who are required to register with FDA identify as part of their registration information each "person who imports or offers for import" the establishments' devices to the United States. This requirement, which would be implemented at proposed § 807.41, is discussed further in section IV.B.3 of this document. In addition, we are proposing a separate definition for the term "person who imports or offers for import" at § 807.3(y). As defined, this term would include an agent, broker, or other entity, that the foreign establishment uses to facilitate the importation of its device into the United States. However, consistent with the legislative history of the Bioterrorism Act, the term "person who imports or offers for import" would not include carriers. We invite comments on our proposed definition of the term "person who imports or offers for import."

#### B. Registration

##### 1. Who Would Be Required To Register?

Section 510(b) of the FD&C Act states that registration requirements apply to owners and operators of establishments engaged in the "manufacture, preparation, propagation, compounding, or processing of medical devices." Section 510(a)(1) of the FD&C Act defines these terms to include "repackaging or otherwise changing the container, wrapper or labeling of any device package in furtherance of the distribution of the device \* \* \*".

The revisions we are proposing would not change the classes of persons required to register, except to specify that all contract manufacturers and sterilizers must register their establishments, regardless of whether they put the device in commercial distribution or instead return it to the specification developer or point of origin.

##### 2. When Would Initial Registration Information Need to Be Provided?

Section 807.21, the provision specifying timeframes for establishment registration, is being renumbered in this

proposal to § 807.22. Proposed § 807.22 would retain the requirement that owners or operators must register each establishment no later than 30 calendar days after entering into an activity that triggers registration requirements under part 807.

Under current § 807.40(c), with certain limited exceptions, a foreign owner or operator must register an establishment before a device manufactured at the establishment may be imported or offered for import into the United States. This proposal would not change the timeframe for initial registration by a foreign establishment.

##### 3. What Information Would Be Required for Registration?

Under proposed § 807.25, all owners or operators would need to provide the following information in order to register their establishments:

a. *Name of the owner or operator of each establishment.* Section 807.3(f) defines the owner or operator as the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment. While the requirement to identify the owner or operator of the establishment is not new, we are addressing it here to provide assistance in identifying the owner or operator for medical device registration and listing purposes.

In practice, the owner or operator usually is the entity that has final responsibility over the device establishment, such as the establishment's parent company or corporate headquarters. For most small device manufacturers who conduct their business activities at the same site as their regulated device activities, this typically is the same name and address as that of the registered establishment itself. In other words, for a business that has only one location where all medical device production activities are conducted and where corporate responsibility for those activities resides, the owner or operator name and address information is the same as the establishment information.

This has often been a source of confusion regarding the information that must be submitted for registration and listing. We invite comments and questions about what constitutes the "owner or operator" of a device establishment for purposes of part 807.

b. *Name, trade name(s), and address of each establishment (proposed § 807.25(b)).* This provision is consistent with section 510(c) of the FD&C Act, which requires owners and operators to register the names and place of business of the establishment. There are no



changes being proposed to this requirement in the revised regulation.

c. *Registration number of each establishment.* Section 510(e) of the FD&C Act authorizes us to assign a registration number to any person or establishment who registers. Under § 807.35(a) of our regulations, we currently assign a permanent registration number to each device establishment when that establishment registers for the first time. The proposed regulation would only change the method of delivery of the FDA registration number to the owner or operator. FDA registration numbers are communicated to the registrant by email after we receive the registration information through the electronic device registration and listing system and it has been verified by the appropriate FDA district office. As there is no physical document to validate and return, FDA no longer sends a validated copy of a form back to the registrant by postal mail.

d. *Name, address, telephone and fax numbers, and e-mail address of the official correspondent for each establishment (proposed § 807.25(e)).* In this document, we continue to require information regarding the official correspondent of the establishment because we need a contact person to be responsible for submitting and keeping the establishment's registration and device listing information current, and to facilitate contact between FDA and the owner or operator. Under proposed § 807.25(e), this information must be kept current and any change in this information must be provided to us within 30 calendar days.

e. *Information for foreign establishments only.* With respect to foreign establishments who are required to register their establishment with FDA, we would require under proposed §§ 807.40 and 807.41, that such establishments submit the name, address, telephone and fax numbers, and e-mail address for the following:

- The U.S. agent;
- Each importer of the establishment's device in the United States that is known to the establishment; and
- Each person who imports or offers for import the establishment's device to the United States.

The name, address, and phone number of the United States agent is information that already must be submitted under current § 807.40(c). We are proposing that owners or operators also be required to provide information regarding importers and persons who import or offer for import the foreign establishment's device because of

changes made to section 510(i) of the FD&C Act by section 321 of the Bioterrorism Act. Section 510(i), as amended, requires foreign establishments to submit as part of their annual registration, among other things, the name of each "importer" of their device that is known to the foreign establishment and also the name of each "person who imports or offers for import" the foreign establishment's device to the United States. We, therefore, expect the person responsible for providing the registration and listing information on behalf of the foreign establishment to undertake appropriate due diligence in gathering and entering the information, which would include identifying and reporting those importers that others in his or her establishment know of or have reason to know of. In addition to identifying them by name, the proposal would require that the foreign establishment provide the address, telephone and fax numbers, and e-mail address of each importer and each person who imports or offers for import to enable us to contact these persons.

We expect that some of the foreign establishments' "importers" will be parties who also are considered "initial importers" as that term is defined in our current registration and listing regulations at § 807.3(g). Under § 807.3(g), the term initial importer means 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 wrapper or labeling of the device of device package. Because initial importers are already required to register, the electronic registration and listing system will permit foreign establishments to use a search mechanism built into the system to identify those importers of the foreign establishment's devices that are also initial importers. Foreign establishments providing information for other types of importers such as retail establishments and end users who are not ordinarily required to register with FDA would have to provide the name, address and contact information for each such importer, except they would not need to identify an end user that is either a consumer or patient, unless the foreign establishment ships its product directly to the consumer or patient.

Because foreign establishments may use different importers and persons who import or offer for import for different devices, in order to collect this information efficiently, the agency proposes to have foreign establishments

provide this information when they are listing their devices. The electronic system will provide an interface for the foreign establishment to identify each product's importers and persons who import or offer for import on a listing-by-listing basis.

The foreign establishment would not be considered registered until all information required under proposed §§ 807.25, 807.40 and 807.41 is submitted. Foreign establishment registration data collected through the electronic registration and listing system will allow us to accurately identify who is making devices, where they are being made, and where they are going within the United States. Having this information is critically important to the nation's ability to prepare for and effectively respond to public health emergencies, including bioterrorism threats and other public health emergencies.

#### 4. What Are the Proposed Requirements for Reviewing and Updating Registration Information?

This proposal would modify and streamline the requirements associated with updating registration information. Currently, the regulations require that owners or operators submit changes to their establishment registration information on Form FDA 2891a at the time of annual registration, or by letter if the changes occur at other times.

Under proposed § 807.22, establishments would access FURLS and review their current registration information online, making changes only where needed. Updating registration information is less time consuming using FURLS because the establishment's current information is easily accessible at all times and only changes to the information already in the system need to be entered into the applicable fields. Previously, the registration and listing forms required that most or all of an establishment's registration and/or device listing information be re-entered on each paper form submitted to FDA.

Some of the specific requirements proposed for updating registration information include the following:

##### a. *Updates of registration information.*

Owners or operators, under proposed § 807.25, would report the following changes no later than 30 calendar days after the change occurs:

- The closing or sale of an establishment;
- Any change in the name or address of an establishment;
- Any change in the name or address of the owner or operator; and
- Any change in the name, address, telephone and fax numbers, or e-mail

address of the official correspondent or the U.S. agent.

We encourage establishments to provide expedited updates as soon as possible after the change occurs, which the new electronic device registration and listing system will facilitate, but no later than 30 calendar days after the change occurs.

b. *Annual review and update of registration information.* Proposed § 807.22 would require that registration information be reviewed and updated annually, during the period beginning on October 1 and ending on December 31, which represents the first 3 months of FDA's fiscal year. This timeframe is consistent with the requirements in section 510(b) and (i) of the FD&C Act as amended by section 222 of FDAAA. Current § 807.21 provides a schedule for the annual registration of establishments during one of four periods of the calendar year (i.e., March, June, August, and November) based on the first letter of the owner or operator's name. Proposed § 807.22 would replace this schedule with the requirement that all owners or operators renew their registration information annually, during the period beginning on October 1 and ending on December 31 of the fiscal year for which they are registering.

All registration information would need to be reviewed and updated each year using FURLS, even when no changes have occurred during the previous year. The phrase "review and update" as used in proposed § 807.22(b) stresses the importance of first reviewing all registration information to determine if any changes have occurred, and then updating the information where needed, or confirming the accuracy of the current information. Under proposed § 807.22, updates must reflect all changes that have occurred since the last update.

When an owner or operator fails to comply with the annual registration or listing requirements, the establishment converts to a "failed to register" or "failed to list" status as applicable. This would include registrants who have not been granted a waiver from electronic registration who attempt to re-register their establishment by submitting a paper-based form or letter. These establishments would retain their failed to register and/or list status until the owner or operator uses the electronic system to review, update, and certify the accuracy of their registration and listing information.

We believe that placing establishments whose owners or operators fail to comply with registration or listing requirements in

one or both of these categories, as applicable, is reasonable given the importance of registration and listing information. To increase the nation's ability to prepare for and respond effectively to public health emergencies, including bioterrorism threats and other public health emergencies, it is becoming increasingly important for owners and operators of device establishments to comply with our registration and listing requirements. With accurate registration and listing information, FDA can more quickly identify where particular types of devices, e.g., respirators or blood tubing, are being made and help ensure that they are available as promptly as possible for a public health emergency. Furthermore, taking steps to increase compliance with these requirements is consistent with section 301(p) of the FD&C Act (21 U.S.C. 331(p)), which makes it a prohibited act to fail to register or list in accordance with section 510 of the FD&C Act.

c. *Type of operation.* We are proposing to have owners or operators enter information about the types of operations or activities conducted at each of their establishments only when they are entering listing information. Before the implementation of FURLS, changing the types of operations or activities required updates to both registration and listing data. This has in some instances led to discrepancies between the types of activities being reported on an establishment's registration forms as compared to the activities being reported on their device listing forms.

FURLS automatically keeps an establishment's registration record current and consistent with its listing information by assigning or removing activities to and from the registration record based on the current active listing information for each device. This practice will help to avoid confusion and conflicts between registration and listing information for a single establishment.

d. *How the information would be submitted.* Proposed § 807.21 would require establishments to submit information to us electronically, unless we grant a waiver under proposed § 807.21(b).

e. *Transfer of device establishment ownership.* Under this proposal, information regarding changes to ownership of device establishments would also be submitted using the electronic device registration and listing system. There would be a selection from the main menu that will appear for the device registration and listing system when accessed through FURLS that will

prompt the user through the process of submitting all information required to report the transfer of ownership.

### C. Listing

#### 1. Who Would Be Required to List Devices?

The changes we are proposing would not change the classes of persons that are required to list devices, except to alter the listing obligations of those contract manufacturers and sterilizers who are currently exempt from listing under § 807.20(a)(2), (c)(1), and (c)(2) because the establishments for whom they make or sterilize devices on a contract basis are the ones who commercially distribute the devices. As stated elsewhere in this document, we are proposing to eliminate this exemption, which will have the effect of requiring all contract manufacturers and contract sterilizers to register and list regardless of who has responsibility for placing the devices into commercial distribution.

Under this proposal, all parties who are required to register would continue to be required to also provide device listings to FDA, with the exception of initial importers. Initial importers currently are not required to submit a device listing for those devices for which the initial importer did not initiate or develop the specifications, or repackaging or relabel the device. We are not proposing to change this practice.

#### 2. When Would Listing Information Be Provided?

Under proposed § 807.22(a), at the time an establishment is initially registered, owners and operators would list any device that the establishment manufactures or otherwise puts in commercial distribution. This provision is consistent with section 510(j)(1) of the FD&C Act, which requires, among other things, that every person who registers with the Secretary under section 510(b), (c), (d), or (i) of the FD&C Act must, at that time, provide the Secretary with a list of the devices being manufactured, prepared, propagated, compounded, or processed by that person for commercial distribution.

Proposed § 807.22(a) and (b) also address providing listing information for devices not previously listed and reviewing and updating information for devices that have already been listed. Previously, owners or operators were required to review and update listing information each June and December and submit all material changes to the device listing information that had been previously submitted.

Although registrants may choose to amend their device listing information at any time throughout the year, under proposed § 807.22(a) and (b), owners and operators would be required to review and update their listing information only once per year, during the annual registration period beginning on October 1 and ending on December 31 of each year. In addition, foreign establishments would continue to be required to submit device listings before their devices may be imported or offered for import into the United States.

### 3. What Listing Information Would Be Required?

The following discussion summarizes the new information that would be required under proposed §§ 807.25, 807.26, and 807.28:

*a. The assigned FDA premarket submission number of the approved application or cleared premarket notification for each device listed that is subject to sections 505, 510, 515, or 520 of the FD&C Act, which includes devices that are not exempt from premarket notification and approval.* In the case of non-exempt products, owners or operators would be required to identify a product's premarket submission number, that is, the number FDA assigned to the 510(k), premarket approval (PMA) application, product development protocol (PDP), humanitarian device exemption (HDE), or new drug application (NDA). Unlike the previous system, which assigned one listing per product code, under the new electronic system (FURLS) each device with a premarket submission number now constitutes a separate listing and is assigned a unique listing number. In FURLS, when the premarket submission number is entered, the product codes that were assigned to the premarket submission based on the FDA premarket review are automatically displayed. This new system helps establishments ensure that the listed product codes match those that appear on the substantial equivalence notification or on the premarket approval letter.

This change, which would be codified in § 807.25(g)(4), generates more unique listing numbers than the previous system, because individual listings are generated for each product subject to a 510(k), PMA, PDP, HDE, or NDA.

*b. Additional types of information required to be provided by foreign establishments.* With respect to foreign establishments only, for devices manufactured, prepared, propagated, compounded, or processed at the establishment, the establishment must identify and provide contact

information for: (1) The U.S. agent, (2) each importer of the foreign establishment's device in the United States that is known to the establishment ("importers"), and (3) each person who imports or offers for import such device to the United States. The requirement for foreign establishments to designate a U.S. agent is already included in the current regulations at § 807.40(b) and this requirement would not change. However, the information regarding importers and persons who import or offer for import currently is not required to be submitted under part 807. Because section 321 of the Bioterrorism Act requires the submission of information about importers and persons who import or offer for import, we are proposing to amend our regulations to conform to the statutory requirements.

In order to make it easier for foreign establishments to provide information about importers and persons who import or offer for import when they are registering and listing with FDA, FURLS includes an interface that allows the foreign establishments to select their importers from the FDA database of registered initial importers, and to enter the names, addresses, and other contact information for any additional importers and persons who import or offer for import (e.g., agents, brokers) who have not previously been entered into the electronic database.

Several of the listing requirements in current §§ 807.25, 807.26, and 807.28 have changed only insofar as how the information would be submitted using FURLS. These requirements include the following:

*c. The current registration number and name of each establishment under the ownership and control of the owner or operator that performs a regulated function to a device.* Proposed § 807.25(g)(1) requires that the owner or operator provide FDA with the registration number(s) for all establishments under his or her ownership or control that perform a regulated function on, to, or for a device. This means the owner or operator does not need to inform FDA of any activity regarding the device that is performed at an establishment that is not under the owner or operator's ownership or control. For example, an owner or operator that develops specifications at one establishment that is under its ownership and control, and then manufacturers the device at another establishment that is also under its ownership and control, must inform FDA about both establishments when listing the device. However, an owner or operator that develops specifications for

a device that is then manufactured by another owner or operator's establishment, i.e., an establishment which is not under its ownership and control, must only identify the establishment where the specifications were developed, when submitting listing information. In this case, the owner or operator would not need to identify the manufacturing establishment.

This requirement, while not new, has in the past been the source of some confusion. To avoid further confusion, FURLS has been designed such that an owner or operator can only submit listing information for establishments under its ownership or control. Under FURLS, the owner or operator selects their establishment(s) from a pick list that only includes establishments under the owner or operator's control.

*d. The product code for all listed devices that are exempt from premarket notification and approval, as well as devices put into commercial distribution prior to May 28, 1976.* Under this proposal, owners or operators listing devices that are considered exempt from premarket notification, "pre-amendment" devices, (i.e., devices put into commercial distribution prior to May 28, 1976), or devices intended for export only, would continue to identify an applicable product code for the device at the time of listing. When submitting listing information using Form FDA 2892, the owner or operator had to make the determination of which products could be listed under their product code and did not require an FDA premarket submission number. However, the new electronic system automatically displays only the product codes for which an owner or operator can create an exempt or export-only listing during the listing process, thereby eliminating the possibility of the owner or operator selecting a product code that requires a premarket submission.

*e. The proprietary or brand name(s) under which the device is marketed.* FURLS accommodates entry of as many proprietary or brand names as are needed for all listings. This is a change from the paper-based system which limited the number of characters available for entry of the proprietary or brand names. The design of the FURLS database and Web interface allows entry of as many proprietary or brand names as may be associated with the listing.

*f. Each activity or process that is conducted on, or done to, the device by the listing owner or operator at each establishment shown on the listing, such as manufacturing, manufacturing for export only, repacking, relabeling,*

*developing specifications, remanufacturing, SUD reprocessing, contract manufacturing, or contract sterilizing.* We are proposing that information about the activities or processes that are performed with respect to a device at each registered establishment such as manufacturing, manufacturing for export only, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, or contract sterilizing, be identified as a part of the listing process only. Previously, we required such information to be submitted on the establishment registration form (under "Establishment Types") and on the device listing form. Consequently, at times there were inconsistencies between the two forms, which led to confusion about the activities actually being conducted at a particular device establishment at any given time, especially as companies added new products or discontinued previously-listed products. By limiting the submission of this information to the listing process, the information available to FDA should become more consistent and accurate because FURLS is designed to automatically conform the establishment registration record to reflect any changes made to the device listing information, including any changes in the types of activities or processes performed at the establishment. For example, if an owner or operator lists a product under product code ABC as being manufactured at Establishment 1, and lists another product under product code DEF as being repacked or relabeled at Establishment 1, then Establishment 1's registration would automatically include manufacturing and repacking/relabeling as activities at the establishment. If the owner or operator were to amend its listing information to reflect that it discontinued the product under product code DEF, the registration data for Establishment 1 would automatically be revised to show Establishment 1 as a manufacturing site only.

We expect this will be a more efficient way to collect this information, and should lessen the burden on the owner or operator, who no longer would be required to enter information about the establishment's operations during both the registration and the listing processes. The owner or operator would no longer be responsible for ensuring that the activities identified in their registration record are consistent with those in their listing records because changes made to the activities included

on their listing records would automatically update the activities on their registration record.

#### 4. What Are the Proposed Requirements for Reviewing and Updating Listing Information?

Previously, establishments had to enter new or revised listing information on Form FDA 2892 and return the form to FDA. Under this proposal, owners or operators would instead be required to access our electronic device registration and listing system (FURLS), review their current listing information online, and make any changes as needed. Updating listing information is less time-consuming under the proposal because owners or operators are able to access their information at any time, and only need to enter data in the fields where there are changes to listing information. It also eliminates the need to mail the form to FDA, and eliminates the return and re-mailing of listing forms when the information initially provided on the form was incorrect or incomplete. The electronic system has automatic validations and edits built in to help ensure that all listing information is complete and correct.

Under proposed § 807.22(b), during the annual review and update of registration information, establishments would be required to provide original listing information for any device that has not been previously listed, as well as updates to listings for devices that have been previously listed.

Under proposed § 807.22(b)(3), owners or operators would review and update their listing information during the period beginning on October 1 and ending on December 31 of each year. This is consistent with the timeframes set forth in the amendments to section 510(j)(2) of the FD&C Act by section 223 of FDAAA.

#### D. Electronic Format

##### 1. How Would Registration and Listing Information Be Provided To FDA?

Under proposed § 807.21, all registration and listing information would be provided to FDA through use of our electronic device registration and listing system, FURLS, with the exception of labeling and advertisement information for a device (when submission of this information is appropriate), and information from those owners and operators who are granted a waiver from the requirement to submit information electronically.

To register their establishment and list their devices using FURLS, owners or operators need to do the following:

- Create an account in the FURLS. If owners or operators already have a

FURLS account as a food or drug establishment, they would update their existing FURLS account to include access to the device registration and listing system;

- Create subaccounts, as necessary, for the official correspondent for each establishment that is being registered;
- Follow the prompts and the help text provided to enter their establishment registration and device listing information; and
- Certify that the information entered is accurate and complete.

Electronic submission of registration and listing information provides a number of advantages over the paper-based submission process. For example:

- We receive more accurate information than with paper submissions. The information received is more consistent and accurate because FURLS includes validation and automated edits to help provide consistency among the data. This also helps eliminate errors of transcription made when we input paper-based data into our old registration and listing database;

- Both for industry and FDA, electronic transmission of the information is easier and more efficient than the use of paper forms. For example, users submitting information receive onscreen, real-time feedback if the information submitted is incomplete, thereby reducing errors and the time and cost of communicating with FDA. Electronic transmission of the information also significantly reduces the time and cost associated with processing paper forms and communicating with industry about errors found on those forms; and

- The registration and listing information available for search and retrieval, both for FDA and industry, is more accurate and up-to-date. Updates may be made to FURLS in real time as opposed to the paper-based system where submissions could take several weeks to arrive at FDA from foreign establishments, then require another week to 10 days to be screened at our mail facility, forwarded to our data entry contractor, and entered in our current database.

##### 2. How Does the Electronic Device Registration and Listing System Work?

Information that is required from owners and operators is submitted to our electronic device registration and listing system (FURLS) over the Internet. The system has a number of features designed to improve the overall accuracy and verifiability of submitted information, and decrease the burden on owners and operators to comply with

FDA's registration and listing regulations. The system is consistent with conventions found on other government sites. Some key features of the system are: (1) Our electronic device registration and listing system (FURLS) is accessible through our FDA Internet site. To use the Web site, you need access to the Internet using a browser. You could arrange for Internet access through one of many available Internet Service Providers (ISPs). You need an e-mail address so we can send you confirmation of submissions and other related information. This e-mail address could be obtained through the ISP or from other sources; (2) prior to accepting registration and listing information from this online system, we authenticate the source (that is, the owner or operator) providing the data. We authenticate entry into the electronic device registration and listing system by establishing user accounts based on current registration information. We also contacted owners or operators of currently registered establishments to identify the single contact person who is responsible for creating and maintaining the owner or operator's account and creating and maintaining any subaccounts that the owner or operator may require for additional official correspondents if more than one establishment is owned or operated by a single entity; and (3) to register and list electronically and to provide updates to your registration and listing information you would go to our Web site and follow the instructional prompts. You sign onto the system by entering the account number, user name, and password obtained by following the procedures on the FDA Web site and e-mailed and paper-mailed to all current owners or operators describing our electronic device registration and listing system. You are prompted to provide general information about the owner or operator and then specific information about each establishment and device as described in the provisions of proposed part 807. When all of the required information has been provided, the official correspondent is notified electronically that FDA has received the information.

### 3. Will FDA Provide Training on How to Submit Registration and Listing Information Electronically?

We provide detailed instructions on our Web-sent e-mail and paper mailings to registered establishments explaining FURLS. These materials explain the electronic process for providing registration and listing information, including step-by-step instructions on

creating user accounts and entering the information that is required under proposed part 807.

### 4. What Language Would Be Used to Provide Registration and Listing Information?

All domestic firms already submit registration to us in English and, in this proposal, we would retain the current requirement under § 807.40(c) that foreign establishments also submit their registration and listing information in the English language. While the requirement has not changed, it has been renumbered as § 807.40(d) to accommodate the revisions to part 807 as described in this document.

### 5. Could the Electronic Format Requirements Be Waived?

Section 510(p) of the FD&C Act, as amended by FDAAA section 224, requires the electronic submission of registration and listing information unless we grant a request for a waiver because the use of electronic means is not reasonable for the person requesting the waiver. Consistent with section 510(p), proposed § 807.21(b) would permit establishments to request waivers from the new electronic submission requirements.

We do not anticipate many waiver requests because the business expenses associated with owning a personal computer, obtaining an e-mail address, and subscribing to Internet access are low. During the first 3 months of operation of the Web-based system, i.e., October through December 2007, we received fewer than 10 requests for waivers from the requirement to submit registration and listing data electronically. As we received data electronically for more than 16,000 establishments for that same period, the waiver requests amount to less than one-tenth of 1 percent of the total number of establishments that have responded.

Under proposed § 807.21(b), we may grant a waiver request upon a showing that use of the Internet to access our Web-based registration and listing system is not reasonable for the person requesting the waiver. This is consistent with the requirement described in section 510(p) of the FD&C Act, as amended by section 224 of FDAAA. Under proposed § 807.21(b), the waiver request must explain why use of the Internet and our electronic registration and listing system is not reasonable for the requestor and must include a telephone number and mailing address where we can contact the person making the request. This information is necessary to contact the requestor and

for FDA to determine whether a waiver can be granted. It should be noted, however, that waiver requests stating that it is not possible for the owner or operator to own a computer will probably not be granted since there are other ways to access the Internet. For example, most public libraries have computers with Internet access that can be used, often free of charge, by members of the public.

In those instances when we do grant a request for a waiver, we plan to provide information at that time regarding how the requestor should submit its registration and listing information.

### E. Miscellaneous

#### 1. What Are the Proposed Requirements for an Official Correspondent and a U.S. Agent?

Under proposed § 807.25(e) owners or operators that are subject to the registration requirements in proposed part 807 would continue to have to designate an official correspondent for each establishment. The official correspondent would be responsible for:

- Entering and updating all registration and listing information for the establishment in the electronic system or, if the owner or operator has been granted a waiver from using the electronic system, providing all registration and listing information for the establishment to FDA via postal mail;
- Serving as the point of contact with FDA on matters relating to the annual registration of the establishment and all updates of registration information;
- Serving as the point of contact with FDA on matters relating to initial device listings and device listing updates, including discontinuances;
- Maintaining a current list of officers and directors for submission to FDA upon FDA's request; and
- The receipt of pertinent correspondence from FDA directed to and involving the owner or operator and/or any of the owner or operator's establishments. Under proposed § 807.25(e), we are also adding the requirement that each owner or operator provide FDA with the name of a contact person at the owner or operator's offices who will be responsible for identifying the official correspondent for each establishment. The owner or operator contact person will be the official correspondent in the event no one else has been properly designated. The contact person would be responsible for establishing and updating the owner or operator's electronic registration and

listing accounts and all subaccounts that may be necessary.

In addition, each foreign establishment is required under our existing regulations at § 807.40(b) to designate a single U.S. agent. This proposal retains that requirement. The U.S. agent's responsibilities include:

- Helping FDA communicate with the foreign establishment;
- Responding to questions concerning the foreign establishment's devices; and
- Helping us schedule inspections.

We would not object if the same individual serves as both the U.S. agent and the official correspondent for a foreign establishment, or if the same individual serves as the U.S. agent for more than one foreign establishment.

We are not proposing to change the requirement that each foreign establishment be limited to designating only one U.S. agent. We interpret section 510(i) of the FD&C Act as allowing only one U.S. agent for each foreign establishment because section 510(i) refers to the U.S. agent in singular, rather than plural, terms. We also interpret section 510(i) of the FD&C Act as requiring that the U.S. agent must be located in the United States. These provisions are also consistent with the use of "U.S. agent" in the agency's interim final rule entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002" (68 FR 58894 at 58915, October 10, 2003).

Currently, the provisions concerning a U.S. agent are set forth in our regulations at §§ 807.3(r) and 807.40(b). Current § 807.3(r) defines U.S. agent as a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. The definition further states that the term "United States agent" excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present. Section 807.40(b) also indicates that the U.S. agent must reside or maintain a place of business in the United States, and adds that if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information to the U.S. agent and this action will be considered as equivalent to giving the same information to the foreign establishment itself.

This proposal would retain the requirements from the existing regulations concerning the U.S. agent.

## 2. What Legal Status Is Conferred by Registration and Listing?

This proposal would retain provisions in our existing regulations, at §§ 807.35(c) and 807.39, addressing the legal status of registrants and their devices. These provisions indicate that registration of an establishment or listing of a device does not denote approval of the establishment, the device, or other devices of the establishment; nor does it mean that a product may be legally marketed. Any representation that creates an impression of official approval or that a device is approved or is legally marketable because of registration or listing would be misleading and would constitute misbranding under section 502 of the FD&C Act (21 U.S.C. 352).

## 3. Would the Proposal Require Electronic Submission of Labeling and Advertisements?

Current § 807.31(e) requires owners or operators to submit labeling and in certain cases advertisements or other information for their device when they are specifically requested to do so by FDA. Currently such information, if requested, would be provided to us in paper format. This proposal would give owners or operators from whom copies of labeling or advertisements are requested under § 807.31 (which we are proposing to redesignate as § 807.26) the option of submitting the information to us either in paper format or electronically. In those instances where the owner or operator chooses to submit the requested information electronically, they would do so by email rather than using FURLs. We intend to indicate in public Docket No. 92S-0251 that we are prepared to accept this information in electronic format.

## 4. What Registration and Listing Information Would Be Made Available for Public Disclosure?

Current § 807.37 pertains to the public availability of registration and listing information. The proposal would revoke the introductory text of current § 807.37(a), which includes a description of the types of forms available for inspection, the addresses at which such forms can be inspected, and the addresses to which requests for verification of registration numbers and requests for locations of registered establishments can be directed. We are proposing to revoke this introductory text because these forms are no longer being used under FURLS. Instead, we intend to continue the current practice of making registration and listing information that is available for public

disclosure accessible from our Web site. We expect that the registration and listing information available on the Web under the new electronic system will not change from that which is currently available. This initiative is consistent with the GPEA and also helps to reduce the number of Freedom of Information Act (5 U.S.C. 552) requests we receive for registration and listing information.

## 5. How Would Part 11 Apply to the Electronic Submission of Registration and Listing Information?

Under part 807 as revised by this proposal, the submission of registration and listing information would be subject to the requirements of part 11 (21 CFR part 11), except for the requirements under § 11.10(b), (c), and (e) and the corresponding requirements under § 11.30.

In the **Federal Register** of March 20, 1997 (62 FR 13430), we published regulations on electronic records and electronic signatures (part 11). Part 11 regulations, among other things, set forth the criteria under which records submitted to us may be submitted in electronic format in lieu of paper records. Section 11.2(b) provides for the submission of electronic records instead of paper records provided the requirements of Part 11 are met and the documents or parts of documents to be submitted have been identified by us in public Docket No. 92S-0251 as being the type of submission we are prepared to accept in electronic format.

Part 11 permits the widest possible use of electronic technology, compatible with our responsibility to promote and protect the public health (62 FR 13430). Part 11 helps to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records. Part 11 also helps to safeguard against the possible repudiation of those records. The controls in subpart B of part 11 are intended to further this purpose.

In the **Federal Register** of September 5, 2003 (68 FR 52779), we announced the availability of a guidance for industry entitled "Part 11, Electronic Records; Electronic Signatures—Scope and Application" (the part 11 guidance). The part 11 guidance explains our current thinking regarding the requirements and application of part 11 and states that we intend to exercise enforcement discretion in the manner specified in the guidance with respect to the validation (§ 11.10 (a)), audit trail (§ 11.10(e) and (k)(2)), record retention (§ 11.10(c)), and copies of records (§ 11.10(b)) requirements of part 11, and any corresponding requirements in § 11.30. In addition, we announced that

we intend to exercise enforcement discretion and do not intend to take (or recommend) action to enforce any part 11 requirements with regard to systems that were operational before August 20, 1997, the effective date of part 11 (commonly known as legacy systems) under the circumstances described in section III.C.3 of the part 11 guidance. The part 11 requirements from which we propose exemptions in this proposal differ from the part 11 requirements for which we intend to exercise enforcement discretion, as described in the part 11 guidance. They differ because the proposed exemptions in this rule are specific to the electronic submission of registration and listing information for devices that would be covered under proposed part 807, whereas the part 11 guidance applies to the maintenance of all electronic records and to all electronic submissions subject to part 11.

With respect to the electronic submission of registration and listing information, as previously noted, we believe, as provided in proposed § 807.25(a), that several of the requirements in subpart B of part 11 are not necessary to further the goals of part 11. Because we control the electronic device registration and listing system (FURLS), certain controls for systems would not apply to the submission of registration and listing information, such as:

- The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency (§ 11.10(b));
- The protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10(c));
- The use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records (§ 11.10(e)); and
- The corresponding controls of § 11.30.

You would be exempt from these subpart B controls because FURLS is designed to ensure the authenticity, integrity, and confidentiality of this information in several ways. For example, we would control the database, and you would only be able to enter and/or revise information in your own account. In addition, the database would contain records of registration and listing information, including the history of all changes to those records, and we could generate accurate and complete copies of these records.

With respect to the electronic submission of labeling or advertisements in connection with device listing, we believe, as provided in proposed § 807.26, that the following requirements in subpart B of part 11 are not necessary to further the goals of part 11:

- The validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records (§ 11.10(a));
- The protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10(c));
- Limiting system access to authorized individuals (§ 11.10(d));
- The use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records (§ 11.10(e));
- The use of operational system checks to enforce permitted sequencing of steps and events, as appropriate (§ 11.10(f));
- The use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand (§ 11.10(g));
- The use of device checks to determine, as appropriate, the validity of the source of data input or operational instruction (§ 11.10(h));
- The use of appropriate controls over certain systems documentation (§ 11.10(k)); and
- The corresponding controls of § 11.30.

We are proposing to exempt the electronic submission of labeling and advertisements from these controls for systems because we believe these requirements are not critical to ensure the quality of the labeling and advertisements that would be submitted under this proposed rule and we do not think it is necessary for industry to expend resources on controls that are not necessary to further the goals of part 11.

With regard to labeling and advertising submissions in electronic format, we recognize there are some differences with respect to the exemptions from part 11 requirements provided in this proposed rule (that is, § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30), and the part 11 requirements set forth in the part 11 guidance for which we intend to exercise enforcement discretion (that is,

§ 11.10(a) through (c), (e), and (k)(2), and the corresponding requirements in § 11.30). Although this proposal does not provide an exemption from § 11.10(b) for the labeling and advertisements, the part 11 guidance announces that we intend to exercise enforcement discretion with respect to that section in the manner described in the guidance.

If this proposed rule is finalized, we intend to identify in public Docket No. 92S-0251 the registration and listing information and the labeling and advertising information specified previously as types of records that we are prepared to accept in electronic format.

#### *F. Conforming Actions*

The proposed changes will not result in changes to any regulations other than part 807.

#### **V. Legal Authority**

We have the legal authority to amend our regulations on foreign and domestic establishment registration and listing for human devices. The statutory basis for our authority includes sections 201, 301, 501, 502, 510, 513, 515, 519-520, 701, 704, 801, and 903 of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 360c, 360e, 360i-360j, 371, 374, 381, and 393); and sections 361 and 368 of the Public Health Service Act (42 U.S.C. 264 and 271) (the PHS Act).

Section 510(c) of the FD&C Act requires every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a device to immediately register with the Secretary his name, place of business, and the establishment. The provisions in section 510(b) and (d) of the FD&C Act require annual registration and registration of additional establishments, respectively. As amended by section 222 of FDAAA, section 510(b) of the FD&C Act requires that annual registration take place during the period beginning on October 1 and ending on December 31 of each year. Section 510(i) of the FD&C Act, as amended by section 222 of FDAAA, requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States, upon first engaging in such activity, to immediately register with the Secretary through electronic means, and thereafter to register annually during the period beginning on October 1 and ending on December 31 of each year. These provisions, together with section 701(a) (among others) of the FD&C Act,



authorize us to require the submission of the registration information specified in the proposal. The information specified in this proposal would help us identify who is manufacturing, repacking, or relabeling devices and where those operations are being performed. In addition, some information (e.g., official correspondent information) would help us communicate with establishments more effectively and schedule inspections more efficiently.

Section 510(j)(1) of the act requires every person who registers to file with the Secretary, at the time of registration, a list of all devices that are being manufactured, prepared, propagated, compounded, or processed by the registrant for commercial distribution. That list must be prepared in the form and manner prescribed by the Secretary and must be accompanied by a copy of labeling (or the label and package insert) and, in some cases, advertising, when requested. Section 510(j)(2) of the FD&C Act, as amended by section 223 of FDAAA, requires each person who registers with the Secretary under this section to report listing information updates once each year during the period beginning on October 1 and ending on December 31 of each year. Listing information gives us a current inventory of marketed devices. These provisions and others of the FD&C Act, together with section 701(a) of the FD&C Act, provide authority for requiring the submission of the listing information set forth in this proposal. The device listing information specified in this proposal would help us: (1) Develop a more current, robust inventory of devices as a counter-terrorism measure; (2) administer our postmarket surveillance programs more effectively; (3) facilitate recalls of products; (4) identify devices in short supply in the event of a national emergency; and (5) identify devices marketed in violation of the FD&C Act.

Section 510(p) of the FD&C Act, as amended by section 224 of FDAAA, requires that registration and listing information be submitted electronically, subject to FDA's grant of waivers to individual requestors who meet the criteria set forth in section 510(p). Electronic receipt of registration and listing information will enable us to shift resources from performing more ministerial tasks, such as data entry, to pursuing important public health objectives such as those described in section I of this document. Electronic receipt of registration and listing information also will help us with the efficient enforcement of the act because we would be able to distinguish

situations where there has been noncompliance with registration and listing requirements from situations where there have been no changes in information. The failure to register or list is a prohibited act under section 301(p) of the FD&C Act and the failure to do either renders a device misbranded under section 502(o) of the FD&C Act.

## VI. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Management and Budget has determined that this proposed rule is a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the burdens imposed by this proposed rule are expected to be minor, the agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

We contracted with the Eastern Research Group, Inc. (ERG), to collect data, interview industry experts, and estimate the costs and benefits of the proposed rule. The analysis in support of the effects of the proposed rule (ERG Memo) is on file with the Division of Dockets Management. ERG identified several very small impacts, both costs

and benefits, associated with this proposed rule. For most of these impacts, ERG found the incremental costs and savings to be so small that it was not a meaningful exercise to generate numeric estimates.<sup>1</sup> ERG was able identify recurring costs associated with this proposed rule, plus additional costs that would not apply to U.S. establishments. After updating ERG's findings with more recent cost information, we find annual costs of \$340,000 associated with this proposed rule, and an additional \$138,000 that would only affect non-U.S. establishments. We were unable to quantify specific benefits attributable to the proposed rule. However, we believe the ultimate use of electronic registration and listing data, the mandate under the Bioterrorism Act to collect additional pieces of registration data, and the requirement under the Bioterrorism Act and FDAAA that information be submitted to FDA electronically justify taking this action.

### A. The Need for Regulation

As discussed elsewhere in this preamble, section 224 of FDAAA amended section 510(p) of the FD&C Act to require establishment registrations and device listings to be submitted to FDA by electronic means unless the Secretary grants a waiver from electronic submission requirements. We currently maintain databases that contain establishment registration and device listing information obtained from owners and operators of device establishments. Prior to FDAAA, these databases relied on paper forms submitted by the owners and operators to us, which were then forwarded by us to a data entry contractor for input into our device registration and listing databases.

Our device registration and listing databases play an important role in our efforts to accomplish many regulatory and statutory objectives. For example, we can use this information to identify device manufacturers to facilitate recalls or information alerts in the case of potential safety concerns. We also use it to plan and conduct inspections, administer postmarket surveillance, generate estimates of the number of businesses that are affected by our rulemaking, and to otherwise exercise competent oversight of the device industry.

The quality and completeness of these databases depends on prompt submission of information and the

<sup>1</sup> ERG memorandum from Cal Franz, et al., September 15, 2008, (hereinafter referred to as ERG Memo), p. 1.

immediate inclusion of the data in our system. Under a paper-based registration and listing system, we were unable to readily verify the accuracy of the information submitted and, in some instances, manufacturers were not timely in informing us of changes. In addition, because we were using physical paper forms, it was possible for information to be mishandled or lost before being added to the system, thereby further reducing the reliability of the databases.

In accordance with FDAAA, the agency began collecting registration and listing information using FURLS, FDA's new Internet-based electronic registration and listing system which became operational on October 1, 2007. The electronic submission of information makes the registration and listing process more efficient for industry and allows us to review and use such information more quickly, thus helping to ensure that medical devices will be safe and effective.

Despite the obvious public health advantages to society of using an electronic device registration and listing system, the private returns alone would not be adequate to move the entire device industry to a new registration and listing format that would meet the requirements of section 510(i) and (p) of the FD&C Act. Because the social benefits are largely external to the firms, the large number of entities operating individually cannot be expected to voluntarily move to a new uniform standard. Few entities would choose to adopt a new format without significant private benefits.

### B. Background

ERG examined FDA's databases of registered device establishments and listed devices and estimates that revisions to the existing device registration and listing regulations would affect approximately 29,370 owner-operators of approximately 33,500 registered device establishments, and 89,200 listed devices. Of the roughly 33,500 registered establishments, approximately 19,700 are registered as domestic and 13,800 are registered as foreign.<sup>2</sup>

Under the existing regulations, with certain exceptions, owners or operators of establishments that engage in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use must, in addition to other requirements, register their establishments and submit listing information for each of their devices in commercial distribution.

Foreign device establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States must comply with the registration and listing requirements, including the requirement to identify a U.S. agent. Until the recent change to electronic submissions mandated by section 224 of FDAAA, all domestic and foreign registration and listing information was submitted using paper forms.

### C. The Proposed Regulation

A major objective of this proposal is to update FDA's regulations at part 807 to reflect the requirement for electronic submission of establishment registration and device listing information as required by FDAAA. A paper-based system of registering and listing is burdensome. It does not facilitate timely updates, which does not allow for the best use of these data in inspections and recalls. We believe that electronic submission of registration and listing information improves the quality and timeliness of information available to FDA. In addition, a system of electronic registration and listing improves the quality and timeliness of information available to health care professionals and consumers. Furthermore, to the extent that these quality improvements to the registration and listing process facilitate device recalls, complement postmarketing surveillance programs, help ensure the safety of imported devices, improve the scheduling and planning of inspections, and otherwise assist the agency in carrying out its statutory and regulatory objectives, there is a broad public health benefit. Moreover, the development and maintenance of high quality databases of information about devices and device establishments would enhance future uses of technology in the delivery of health care. An electronic database that contains current and accurate information about devices could, for example, facilitate the development of technology that would allow for communication among devices, giving them additional functionality and the potential for interoperability.

This proposed regulation would also slightly modify the types of information that would need to be submitted as registration and listing information. However, these modifications would be minor and are generally consistent with achieving a more accurate and useful database of device industry information.

### D. Estimated Impacts

ERG reviewed the proposed registration and listing regulation,

comparing it to the current provisions, and projected the impacts of the proposed regulation. A memorandum prepared by ERG based on this review identifies eight areas where revisions to the current device registration and listing provisions may affect the cost of compliance.<sup>3</sup> These impacts would stem from provisions associated with:

- The creation of an account on FURLS;
- The requirement for submission of additional information as part of the annual registration process;
- Modifications to requirements relating to registration information updates;
- The requirement for submission of additional information when listing a device;
- Changes relating to the requirement for semiannual review and update of device listing information;
- The waiver from the requirement to register and list by electronic means;
- The proposed elimination of the exemptions from registration and listing requirements for foreign establishments whose devices enter a foreign trade zone and are re-exported from the foreign trade zone without having entered U.S. commerce and the exemption for devices that are imported under section 801(d)(3) of the FD&C Act (import-for-export provision); and
- The proposed elimination of the exemption from registration and listing requirements for contract manufacturers and contract sterilizers who do not commercially distribute the devices.

Because most of the identified regulatory impacts only slightly increase or decrease the costs of registering and listing, sometimes involving offsetting impacts, we present the impacts grouped by the eight impact areas identified previously, as opposed to trying to present the impacts as distinct groups of costs and benefits.

#### 1. Creation of FURLS Accounts

Under the proposed rule, establishments would go through the one-time process of creating a FURLS account. According to ERG, the costs associated with setting up the FURLS account are negligible.<sup>4</sup>

#### 2. Changes to Annual Registration Information

This proposed rule could affect the burden on establishments by changing the information they submit in the annual registration process. ERG found that differences in the information collected currently and under the

<sup>2</sup> See ERG, appendix B, table 1.

<sup>3</sup> ERG memo, p. 3.

<sup>4</sup> ERG memo, p. 5.

proposed rule would be minor and should not increase the time spent completing the registration.<sup>5</sup> Some of the additional information is already submitted voluntarily. For example, the e-mail addresses for the establishment's official correspondent and owner-operator, as well as the universal resource locator (URL) for the establishment's Web site, are already being collected. There would be little, if any additional burden for those establishments not currently providing this information. There would be modest savings associated with the annual registration process, as establishments would be able to access and edit registration information online and would no longer have to wait for physical forms to be mailed from FDA, review them, make edits, and mail the forms back to FDA.

As amended by section 321 of the Bioterrorism Act, section 510(i) of the FD&C Act requires foreign establishments whose devices are imported or offered for import to the United States to identify and provide contact information for importers of the establishment's device that are known to the establishment and also those persons who import or offer for import the device into the United States. According to the ERG memo, foreign establishments identifying importers known to them and persons who import or offer for import the establishments' devices would typically be identifying one or two entities of each type with readily available contact information, so the impact would be negligible.<sup>6</sup> OMB Circular A-4 directs us to carefully evaluate new U.S. rules that might act as non-tariff barriers to imported goods. As the burden to these foreign establishments would be quite small and would not have a significant adverse effect on trade, the impact on U.S. consumers from this provision would be negligible.

### 3. Changes Relating to the Requirement to Update Registration Information

Under proposed § 807.22(b)(2), establishments would be required to update their registration within 30 days if their registration information were to change. Current § 807.26 requires that establishments update registration information for a change in ownership or a change in the location of the establishment. As the proposed rule includes a broader set of circumstances requiring a mandatory update, it has the potential to be slightly more burdensome. Under the proposed rule,

however, establishments would provide updates electronically, as opposed to submitting such information to FDA using a paper form as required by current § 807.26. ERG found that the ability to submit updated information through FURLS rather than completing and mailing paper forms would result in a net reduction in administrative burden and, therefore, a cost savings to establishments. ERG did not quantify the amount of the estimated savings, but we feel it would roughly negate any increase in burden from the increased likelihood of a mandatory update.

### 4. Requirement for Additional Device Listing Information

Under proposed § 807.25, establishments would be required to submit additional information, including 510(k) numbers and HDE numbers among the types of premarket submission numbers submitted to FDA for non-exempt devices. Establishments would also submit all proprietary and brand names under which each device is marketed. Although the agency already collects proprietary or brand names as part of device listings, the device listing form specified for use under the existing regulation has a single block of 80 characters for proprietary and brand names, which may have been restricting the amount of information establishments have been providing. In contrast, establishments using FURLS to list their devices have an unlimited amount of space within which to provide information and therefore could submit more data. According to the ERG memo, device listings would rarely have more than three proprietary or brand names, so the additional information that establishments would be providing under the proposed rule would be limited.<sup>7</sup>

Under proposed § 807.25(g)(4), establishments also would be required to submit 510(k) and HDE numbers for non-exempt devices as part of the listing process. This information has been collected by FDA on a voluntary basis since 2005. It is our experience from processing these forms that most establishments submitting device listings since this practice began in 2005 already provide 510(k) and HDE numbers. Because these establishments already are complying with the proposal, they would not face an additional burden as a result of this new requirement. However, there was an additional burden associated with providing 510(k) and HDE numbers for those devices listed prior to 2005.

Because we have already begun to collect information on these devices electronically, much of this one-time burden has already been incurred. Based on a query of non-exempt listings included in FDA's registration and listing database, FDA estimated that 9,300 owners or operators would provide submission numbers for approximately 31,000 device listings. We believe that affected owners or operators needed only a few minutes to look up this information from readily available sources.<sup>8</sup> ERG did not attempt to quantify this very small burden, but noted that the inclusion of the 510(k) number in the device listing would result in significant benefits. Such information would improve our postmarket surveillance efforts by permitting devices to be tracked based on the submission number assigned to the particular device, as opposed to the previous method of tracking based on the reported product codes which did not necessarily correspond to the product codes under which a device was cleared. Also, having the registrant supply the premarket submission number and FDA determine the appropriate product code saves time, as incorrect product codes can lead to delays in listing.

### 5. Changes Relating to Review and Update of Device Listings

Section 510(j)(2) of the FD&C Act, as amended by section 223 of FDAAA, now requires device listings to be updated once each year during the period beginning on October 1 and ending on December 31. Previously, as reflected in the current registration and listing regulations, registrants had to review and update their device listings on a semiannual basis, during June and December. In the past, FDA has not strictly enforced this requirement but has encouraged establishments to update their listings throughout the year whenever information has changed. Thus, although the required updates would be less frequent and less burdensome, we recognize the potential for a minor impact associated with increased enforcement of an existing requirement. We believe any additional impact would be extremely small, and we do not attempt to quantify it.

### 6. Requests for a Waiver from Submitting Information Electronically

Under the proposed rule, parties for whom registering and listing by electronic means is not reasonable may request a waiver from FDA. Because one would only need to have access to a

<sup>5</sup> ERG memo, p. 6.

<sup>6</sup> ERG memo, p. 5.

<sup>7</sup> ERG memo, p. 5.

<sup>8</sup> ERG memo, p. 6.

computer, Internet access, and an e-mail address to register and list by electronic means, we do not anticipate that we will receive many requests for waivers.

For the first few months of operation (i.e., October through December 2007) of the Web-based system, FDA received fewer than 10 requests for waivers from the requirement to submit registration and listing information electronically. As FDA received electronic submissions for more than 16,000 establishments over that period, these requests amount to about 0.06 percent of the total number of establishments that responded.

Based on information taken from our databases as of October 2007, FDA estimated there were 29,370 owners or operators who collectively registered a total of 33,490 device establishments. If 0.06 percent of the 33,490 total device establishments would request waivers from FDA, there would be 20 requests ( $33,490 \times 0.0006$ ). We estimate that the annual burden on these establishments would be an hour of time from a mid-level manager to draft, approve, and mail a letter. Assuming a burden of 20 hours and a labor cost of \$41 per hour including benefits, the cost for all affected establishments would be \$820 ( $\$41 \text{ per hour} \times 20 \text{ hours}$ ).<sup>9</sup> This estimate may overstate the actual burden, as we received only nine waiver requests in 2008.

We anticipate a small number of additional firms would enter the device industry over the next several years and would need to list and register. To the extent that a small fraction of these firms would request waivers, there may be small additional costs in the future.

#### 7. Elimination of Exemptions for Some Foreign Establishments

Under current § 807.40(a), foreign establishments are not required to comply with the registration and listing requirements if their device enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U.S. commerce. As previously discussed, the proposed rule would eliminate the exemption from registration and listing requirements for such establishments.

Current § 807.40(c), which states that no device may be imported or offered for import into the United States unless the device is listed and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment, also states that this

restriction does not apply to a device imported under section 801(d)(3) of the FD&C Act ("import-for-export" provision). As previously discussed, we are proposing to eliminate the exemption from registration and listing requirements for devices imported under section 801(d)(3). This means such devices would have to be listed and the foreign establishments that manufacture these devices would have to register with FDA. ERG estimates that the burden of listing would be 2.5 hours per affected device. Assuming an hourly labor cost of \$41 per hour, the cost of this provision to foreign establishments would be \$103 per device.

ERG has reviewed the databases maintained by FDA's Division of Import Operations and Policy and found that 1,344 shipments of devices entered the United States under the "import-for-export" provision in 2006.<sup>10</sup> This figure represents approximately 0.13 percent of the device shipments to the United States. If each of these shipments required establishment registration and device listing, the cost to foreign exporters would be less than \$138,000 ( $1,344 \text{ shipments} \times 2.5 \text{ hours per shipment} \times \$41/\text{hour}$ ). These are one-time costs, as subsequent shipments of the same device would not require an additional registration and listing. ERG concludes foreign establishments may incur future costs if there are shipments of devices not previously listed and assumes the estimated first year cost is incurred annually. We believe future annual costs would be substantially less than \$138,000 but we do not attempt to quantify them.

ERG was unable to obtain information on the number of devices and firms affected by the loss of the exemption for devices imported into foreign trade zones. We believe the impact of this loss of exemption on individual foreign firms would be very small, but welcome comment on this issue.

Domestic device establishments would not face a substantial burden as a result of the elimination of these exemptions. As these devices are not intended for U.S. commerce, there would be no impact on the domestic market for these devices. Moreover, based on the small cost per affected device, we believe the elimination of these exemptions would have a negligible impact on U.S. industries doing "import-for-export" and operating in foreign trade zones.

For this analysis, we assume that the foreign establishments that would be losing these exemptions are foreign entities and not merely a foreign

presence of a domestic entity. We lack detailed information on these establishments and welcome comment on this issue.

#### 8. Elimination of Registration and Listing Exemptions for Contract Manufacturers and Sterilizers Who Do Not Commercially Distribute the Devices

Under current § 807.20(a)(2), (c)(1), and (c)(2), contract manufacturers and contract sterilizers are exempt from registration and listing obligations if they make or sterilize a device according to another person's specifications for commercial distribution by the person who developed the specifications. This proposed rule would eliminate the exemption from registration and listing for contract manufacturers and contract sterilizers who do not commercially distribute. This means that those contract manufacturers and contract sterilizers that currently do not register or list would be required to do so. Moreover, because there are recurring obligations associated with registration and listing, these firms would bear an additional annual burden.

According to our registration and listing database, as of October 2007, there were 1,304 registered contract manufacturers who had not previously listed any products. Of these 1,304 establishments, 736 re-registered in 2006. We also believe there may be contract manufacturers not registered that would be registering for the first time because of the loss of exemption. We do not know the number of contract manufacturers that would be required to register and list, but for the purposes of this analysis, we estimate that 736 establishments that would need to register and initially list products. We invite comment on this estimate.

Based on the October 2007 estimates, the registration and listing database contains about 89,200 listed devices and approximately 33,500 registered establishments, or about 2.66 devices per establishment. If that ratio were to hold for the estimated 736 affected contract manufacturers, we would expect 1,958 additional device listings under the proposed rule.

Between 1999 and 2006, there was an average of 306 initial contract manufacturer registrations each year. We therefore estimate 306 additional contract manufacturers would initially register in 2008 (for fiscal year 2009) and would also incur costs to list their devices, for a total of 1,042. At 2.66 devices per establishment, this would

<sup>9</sup> We use a mean wage rate of \$31.55 for compliance officers in the medical equipment and supplies manufacturing industry and add 30 percent for benefits.

<sup>10</sup> ERG memo, p. 10.

result in 814 additional listings, for a total of 2,772.<sup>11</sup>

According to our registration information, fewer than 160 establishments perform contract sterilizations only. Of these, 116 do not list devices. Our registration and listing database includes 533 listings for 114 contract sterilizers, or about 4.68 devices per establishment. Under the proposed rule, the 116 contract sterilizers who currently register would also have to list. Assuming these contract sterilizers would list 4.68 devices per establishment, this would result in 543 additional listings.

ERG estimates that the process of registration and listing would require 2.5 hours of time per listed device each year.<sup>12</sup> At a labor rate of \$41 per hour, including benefits, the cost would be \$103 per device or about \$270 per contract manufacturing establishment (\$103 per listing x 2.66 listings) and \$480 per contract sterilizing

establishment (\$103 per listing x 4.68 listings). Across all affected contract manufacturers, including those registering for fiscal year 2009, the cost would be a recurring \$284,000 (\$41 per hour x 2.5 hours x 2,772 listings). For contract sterilizers, the cost would be \$56,000 (\$41 per hour x 2.5 hours x 543 listings). Thus, the impact on contract manufacturers and contract sterilizers would be an annual \$340,000 (\$284,000 + \$56,000). We recognize that we may not be aware of some contract sterilizers that have never registered. We believe there are few if any such firms and do not account for them in our analysis, but invite comment on this issue.

The loss of the exemption for contract manufacturers and sterilizers who do not commercially distribute the devices will not only result in social economic costs, but will also result in transfers associated with the payment of user fees. Contract manufacturers and sterilizers that are required to register

will also be required to pay user fees. According to section 212 of FDAAA, the Fiscal Year (FY) 2009 establishment registration fee is \$1,851. At that rate, we estimate FY 2009 fees of \$2.14 million, \$1.93 million paid by the 1,042 contract manufacturers and \$215,000 paid by the 116 contract sterilizers.

Table 1 of this document summarizes the projected quantified impacts of this proposed rule. The total annual costs are \$340,000. Foreign establishments would face an additional annual burden of \$138,000 due to the loss of the exemptions from registration and listing requirements relating to devices entering a foreign trade zone that are later re-exported without having entered U.S. commerce and devices that are imported into the United States under section 801(d)(3) of the FD&C Act. There would also be a transfer of \$2.14 million in additional user fees paid by contract manufacturers and sterilizers.

TABLE 1.—PROJECTED IMPACTS OF THE PROPOSED RULE

Establishment Category	No. of Affected Establishments/Devices	Incremental Time	Cost per Hour <sup>1</sup>	Total Annual Cost <sup>3</sup>
Requests for a Waiver from Submitting Information Electronically	20 establishments	1 hr	\$41	\$820
Foreign establishments shipping to United States under import-for-export and to foreign trade zones	none <sup>2</sup>	2.5 hrs	\$41	\$0 <sup>2</sup>
Elimination of Exemptions for Contract Manufacturers	2,772 devices, 1,042 establishments	2.5 hrs	\$41	\$284,000
Elimination of Exemptions for Contract Sterilizers	543 devices, 116 establishments	2.5 hrs	\$41	\$56,000
All other	negligible	--	--	negligible <sup>3</sup>
Total	1,178 establishments 3,315 devices	--	--	\$340,000

<sup>1</sup> Average hourly wage for medical equipment and supplies compliance officer, adjusted for benefits.

<sup>2</sup> Provision would not be expected to affect U.S. establishments. An estimated 1,344 foreign establishments would face additional annual costs of \$138,000.

<sup>3</sup> Estimated incremental time costs are offset by incremental time savings.

TABLE 2.—ECONOMIC TRANSFERS ASSOCIATED WITH THE PROPOSED RULE

From	To	Description	Cost per Entity	Total Cost
1,042 Contract Manufacturers and 116 Contract Sterilizers	U.S. Government	Establishment Registration Fees	\$1,851	\$2.14 million

The proposed rule would result in benefits associated with an electronic registration and listing database that would provide more up-to-date and complete information. The electronic registration and listing database system could also support future medical and

health information technology initiatives. The proposed rule would increase the efficiency of the registration and listing process by eliminating all or nearly all paper submissions. With registration and listing in an electronic format, we are able to review the

submitted information more quickly and can contact submitting firms immediately through email if any additional information is needed. In addition, having a database of registered establishments and listed devices that is more accurate and complete can

<sup>11</sup> We do not follow the assumption in the ERG memo that half of these contract manufacturers would not register and pay user fees.

<sup>12</sup> ERG memo, p. 9.

increase patient safety. For example, an electronic database that includes 510(k) clearance numbers and current product codes for devices would help facilitate timely notification of recalls of certain unsafe devices and prompt identification of the affected manufacturers.

Although the scope of the proposed rule does not extend beyond registration and listing, the resulting high-quality, electronic database would facilitate future uses of technology for the public benefit. A current electronic database of device information could, for example, facilitate the development of future devices utilizing wireless connectivity and the interoperation of such devices with hospital information systems, or with handheld personal digital assistant (PDA)-type clients used by health care providers or those managing hospital inventories.

Additionally, having a paper-based registration and listing system is inconsistent with section 510(p) of the FD&C Act, as amended by section 224 of FDAAA, and might deter the medical device industry and healthcare providers from investing in new initiatives that would make use of electronic device listing and establishment registration data.

#### *E. Regulatory Flexibility Act*

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The impact of this proposed rule is almost entirely attributable to the requirement that contract manufacturers and contract sterilizers register and list. We have estimated the impacts on small entities and find that the costs associated with registering and listing would not be a significant burden for even the smallest of contract manufacturers and contract sterilizers. Moreover, failing to remove this exemption for contract manufacturers and sterilizers would reduce the benefits potentially realized from this proposed rule. These benefits would include improving the quality and timeliness of information, facilitating device recalls, complementing postmarket surveillance programs, ensuring the safety of imported devices, and improving the scheduling and planning of inspections. Requiring that contract manufacturers and sterilizers register and list allows for the appropriate oversight of these types of facilities. For other elements of this proposed rule, the costs per entity are very small and we do not believe that this proposed rule would have a

significant economic impact on a substantial number of small entities.

As described earlier in this preamble, this proposed rule would revise the agency's regulations at part 807 to make them consistent with the requirement under FDAAA that the agency shift to an electronic registration and listing format. The incremental costs to establishments making this switch to electronic registration and listing are so small as to be difficult to quantify. Certain elements of the proposed rule may be burdensome to some entities, but these incremental burdens are estimated to be extremely small. The cost of submitting a waiver claiming electronic listing and registration to be unreasonable would be an estimated \$41. The cost of registering and listing a device because of the loss of the exemptions from registration and listing requirements for devices imported into foreign trade zones or imported under section 801(d)(3) of the FD&C Act is not expected to have an effect on domestic establishments. Other elements of the proposed rule involve the submission of information not currently required but readily available and the estimated cost of compliance would be so small as to be difficult to estimate.

Contract manufacturers and contract sterilizers who do not commercially distribute the devices they make or sterilize would be faced with a new requirement to register and list. We do not know how many of the affected contract manufacturers and contract sterilizers would be categorized as small. As shown in table 1 of this document, we estimate 1,042 affected contract manufacturers and 116 affected contract sterilizers. Our internal databases include some contract manufacturers and sterilizers that have in the past voluntarily registered. A review of the contract sterilizers in this database indicate that many are described in external databases as being part of NAICS code 339113 (Surgical Appliance and Supplies Manufacturing). Because of the specific expertise, capital requirements, and economies of scale associated with contract sterilization, we expect contract sterilizers would have more employees and more revenues per employee than would a typical establishment in this class. Medical device contract manufacturers fit in NAICS code 339112 (Surgical and Medical Instrument Manufacturing). For both of these industry classifications, the U.S. Small Business Administration has defined a

small business as one with 500 or fewer employees.<sup>13</sup>

According to the U.S. Census, there are 1,352 establishments in class 339112 with 1,302 of them (96 percent) having fewer than 500 employees.<sup>14</sup> Census information on class 339113 lists 1,845 establishments, with 1,805 of them (98 percent) having fewer than 500 employees.<sup>15</sup> Applying these profiles to our estimated contract manufacturers and contract sterilizers, there would be 1,000 small affected contract manufacturers (96 percent of 1,042) and 114 small affected contract sterilizers (98 percent of 118).

For class 339112 covering contract manufacturers, we consider the smallest establishment group with one to four employees. There are 388 establishments with a total of 839 employees and a total value of shipments of approximately \$130 million. Average revenue per employee is approximately \$150,000. The average establishment in this group has 2.2 employees and receipts of \$331,000. As discussed in section V.I.D of this document, establishment registration user fees are \$1,851 for FY 2009. As shown in table 1 of this document, the estimated annual burden of listing a device is 2.5 hours at \$41 per hour, or \$103. A small contract manufacturer with a single listed device would face an annual burden of \$1,851 plus \$103, or \$1,954, which is 0.59 percent of annual revenues.

Assuming the smallest contract sterilizers have five to nine employees, that particular group in class 339113 has 320 establishments with a total of 2,165 employees and a total value of shipments of approximately \$380 million. Revenue per employee is approximately \$175,000. The average establishment has 6.8 employees and receipts of \$1.2 million. Contract sterilizers would face an annual establishment fee of \$1,851 plus a cost of \$103 per listed device. A small contract sterilizer with two listed devices would face an annual burden of \$1,851 plus \$2,057, or 0.17 percent of annual revenues.

<sup>13</sup> U. S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," August 22, 2008, [http://www.sba.gov/idc/groups/public/documents/sba\\_homepage/serv\\_sstd\\_table.pdf.pdf](http://www.sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_table.pdf.pdf).

<sup>14</sup> U.S. Census Bureau, 2002 Economic Census, "Surgical and Medical Instrument Manufacturing: 2002," Table 4, p. 4, released December 2004, <http://www.census.gov/prod/ec02/ec0231i339112.pdf>.

<sup>15</sup> U.S. Census Bureau, 2002 Economic Census, "Surgical Appliance and Supplies Manufacturing," Table 4, p. 4, released December 2004, <http://www.census.gov/prod/ec02/ec0231i339113.pdf>.

A \$41 burden associated with a waiver request would be about 0.01 percent of revenues for a small entity with revenues in the hundreds of thousands of dollars. As discussed earlier in this section and in section V.I.D of this document, other impacts associated with this proposed rule are all extremely small. We therefore tentatively conclude that the proposed rule, if issued, would not have a significant impact on a substantial number of small entities. We also believe affected entities currently possess the skills required to comply with the provisions of this proposed rule. FDA requests comment on the issue of whether this proposed rule would have a significant impact on a substantial number of small entities.

FDA considered regulatory alternatives such as not regulating and not requiring registration and listing by contract manufacturers and contract sterilizers who do not commercially distribute devices. As explained earlier in this preamble, the electronic submission of information is mandated under FDAAA. Section A discusses the need to regulate in greater detail. The benefits associated with agency oversight of contract manufacturers and contract sterilizers justify the estimated costs of requiring that they register and list.

## VII. Paperwork Reduction Act of 1995

This proposed rule 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). A description of these provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

### Implementation of Sections 222, 223, and 224 of the Food and Drug Amendments Act of 2007 (OMB Control No. 0910–0625)—Revision

FDA is proposing to amend its regulations governing medical device establishment registration and device listing. The proposed revisions would modify FDA's current regulations at part 807 to reflect recent statutory amendments to the device registration and listing provisions of the FD&C Act. FDAAA, which was enacted on September 27, 2007, amended section 510 of the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms, and also specified the timeframes when establishments are required to submit such information. In accordance with FDAAA, the agency launched FDA's Unified Registration and Listing System (FURLS), an internet-based registration and listing system. FDAAA requires electronic submission of device registration and listing information unless FDA grants a waiver request.

In addition, this proposal would facilitate FDA's collection of additional registration information from foreign establishments as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). It also would update certain provisions in part 807 to improve the quality of registration and listing information available to FDA. FDA relies on having complete and accurate registration and listing information in order to accomplish a number of important public health objectives.

#### A. Statutory Compliance

To comply with the statutory deadline under the provisions of FDAAA for medical device establishment registration and device listing by electronic means, including waiver provisions, FDA initially obtained a 6-month OMB approval of the collection of information requirements under the emergency processing provisions of the Paperwork Reduction Act (the PRA), and subsequently obtained a 3-year approval of these requirements under the same assigned OMB Control No. 0910–0625. With OMB approval of the collection of information requirements, FDA took several actions: (1) Developed an electronic form "Device Registration and Listing Module," Form FDA 3673 and (2) developed and implemented the

guidance entitled "Guidance for Industry and FDA Staff—Implementation of Medical Device Establishments Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007." This guidance among other things explained the recent changes in the device registration and listing program and the process (instructions) for using FURLS, an Internet-based registration and listing system.

#### B. Transition Process From Paper to Electronic Submission

The information collection requirements for paper submissions were approved under the assigned OMB control number 0910–0387 with the associated Forms FDA 2891, 2891a, and 2892. Upon approval of electronic registration and listing information collection requirements under FDAAA, FDA: (1) Replaced the paper forms FDA 2891, 2891a, and 2892 with the electronic data collection instrument, Form FDA 3673; (2) revised the collection of information 0910–0387 for paper submissions to include only nonregistration and listing paperwork requirement, thereby reducing the annual reporting burden requirements (the registration and listing requirements under FDAAA were updated as a revision to the collection 0910–0625); (3) following notice in a June 17, 2007, letter to firms, shut down the manual data entry system on September 15, 2007, and began using the new electronic system on October 1, 2007; and (4) sent each firm a letter on October 1, 2007, providing account and password information for the new system.

*Description:* In accordance with the collection of information entitled "Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices," medical device establishment owners and operators will be required to electronically submit establishment registration and device listing information.

Section 510(c) of the FD&C Act requires owners or operators of domestic establishments upon first engaging in the "manufacture, preparation, propagation, compounding, or processing" of a device or devices in those establishments to immediately register their name and place of business and such establishment. Section 510(a)(1) of the FD&C Act defines the term "manufacture, preparation, propagation, compounding, or processing" to include "repackaging or otherwise changing the container, wrapper, or labeling of any \* \* \*



device package in furtherance of the distribution of the \* \* \* device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.”

Section 510(a)(2) of the FD&C Act mandates that the term “name” include, among other things, the name of each partner of a partnership, and the name of each corporate officer and director of a corporation. An owner or operator of a registered establishment must also immediately register any additional establishment that he owns or operates in any State and in which he begins the “manufacture, preparation, propagation, compounding, or processing” of a device (section 510(d) of the FD&C Act). An owner or operator of any establishment that engages in these activities must also re-register its establishment once each year during the period beginning on October 1 and ending on December 31 of each year (section 510(b) of the FD&C Act, as amended by FDAAA).

Section 510(i) of the FD&C Act contains certain registration requirements pertaining to foreign establishments (e.g., submission of the name of each importer of the establishment’s device in the United States that is known to the establishment, submission of the name of each person who imports or offers for import the establishment’s device to the United States for purposes of importation). Section 510(g) of the FD&C Act provides for certain exemptions from the registration requirements. In addition, section 510(p) of the FD&C Act, as amended by FDAAA, requires the electronic submission of device registration and listing information unless the Secretary grants a request for a waiver because use

of electronic means is not reasonable for the person requesting the waiver.

Section 510(j)(1) of the FD&C Act requires that every person who registers must, at the time of registration, submit a list of all devices that are being manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution which have not been previously listed by him or her. This information must be submitted in the form and manner prescribed by the Secretary (section 510(j)(1) of the FD&C Act). Prior to FDAAA, section 510(j)(2) of the FD&C Act required certain changes in listing information to be reported every June and December, including any material changes in information previously submitted under the listing provisions. This information must now be provided only once each year during the period beginning on October 1 and ending on December 31.

Section 510(e) of the FD&C Act permits the Secretary to prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices under section 510(j) shall list such devices in accordance with such a system. The disclosure provision in section 510(f) of the FD&C Act requires the Secretary to make available for inspection any registration filed under section 510. Section 510(f) also provides that certain listing information must be exempt from disclosure unless the Secretary finds that such exemption would be inconsistent with protection of the public health.

Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: Identification of establishments

producing marketed medical devices, identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, facilitation of recalls for devices marketed by owners and operators of device establishments, identification and cataloging of marketed devices, administering postmarketing surveillance programs for devices; identification of devices marketed in violation of the law; identification and control of devices imported into the country from foreign establishments; and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act.

The electronic collection of establishment registration and device listing information from medical device establishment owners and operators also furthers the purpose of several statutes, including: The FDAAA, the Bioterrorism Act, MDUFMA, and GPEA.

*Description of Respondents:* Owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The total annual estimated burden imposed by this collection of information is 103,536 hours annually.

FDA estimates the burden of this collection of information as follows:

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.20(a) <sup>3</sup>	3,673	800	1	800	0.75	600
807.21(a) <sup>3</sup>	3,673	125	1	125	0.5	63
807.21(b) <sup>2</sup>		20	1	20	1	20
807.21(b) <sup>3</sup>		1	1	1	1	1
807.22(a) <sup>3</sup>	3,673	2,566	1	2,566	0.5	1,283
807.22(b)(1) <sup>3</sup>	3,673	29,100	1	29,100	0.75	21,825
807.22(b)(2) <sup>3</sup>	3,673	3,000	1	3,000	0.5	1,500
807.22(b)(3) <sup>3</sup>	3,673	24,870	1	24,870	1	24,870
807.26(e) <sup>3</sup>		100	1	100	1	100

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.34(a) <sup>2</sup>		20	1	20	1	20
807.34(a) <sup>3</sup>		1	1	1	1	1
807.40(b)(2) <sup>3</sup>	3,673	50	1	50	0.5	25
807.40(b)(3) <sup>3</sup>	3,673	1,836	1	1,836	0.25	459
807.41(a) <sup>3</sup>	3,673	11,348	1	11,348	0.5	5,674
807.41(b) <sup>3</sup>	3,673	11,348	1	11,348	0.5	5,674
Total one time burden						40
Total recurring burden						62,075

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> One Time Burden

<sup>3</sup> Recurring Burden

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
807.25(d) <sup>2</sup>	33,490	1	33,490	.25	8,373
807.26 <sup>2</sup>	16,524	4	66,096	.5	33,048
Total					41,421

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Recurring burden.

The currently approved reporting and recordkeeping burden for electronic registration and listing under OMB No. 0910–0625 is 71,319. The estimated reporting and recordkeeping burden for electronic registration and listing under the proposed rule is 103,536 hours, an increase of 32,217 hours. This increase is due to an under estimate of the original burden estimate for 0910–0625 and the incremental increase of respondents no longer exempt from these requirements.

Burden estimates are based on recent experience with the existing medical device registration and listing program and the economic analysis provided by ERG. The changes to the actual data collected are, with one exception, very minor. We are assuming that it will take approximately the same amount of time to enter the data online using FURLS as it does to use the portable document format (PDF)-enabled forms that had been used for initial establishment registration prior to FURLS becoming operational in October 2007. Any additional burden associated with creating and using the Web-based system accounts (as shown in table 3 of this document under § 807.21(a)) should be offset by the elimination of the need to re-enter identifying information

concerning the establishment or product every time registration or listing information is updated, which was the case when updating such information using the PDF-enabled forms.

The recurring burden for the new data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on the ERG memo. This report stated that foreign establishments would typically be identifying one or two importers and one or two persons who import or offer for import with readily available contact information.

The estimates for creation of new user accounts under § 807.21(a) are based on the current number of owners or operators, and experience in account creation using the existing FURLS for Food Facility Registration. The estimates for the recurring years assume a similar increase in the number of new owner or operator numbers as were created in FY 2006.

The estimate for § 807.25(d) in table 5 of this document (recordkeeping burden) reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only

when requested by FDA. However, it is assumed that some effort will need to be expended to keep such lists current.

The requirements shown in table 5 for proposed § 807.26 (renumbered from § 807.31), have not changed based on this revision to the registration and listing regulations. They reflect other recordkeeping requirements for devices listed with FDA, and the requirement to provide these records when requested by FDA. They are based on experience FDA has had with the existing regulation.

This proposed rule also refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in § 807.35(b) have been approved under OMB control number 0910–0052. This rule is not going to impact the burden in 0910–0052 that is already accounted for in that information collection.

To further clarify and track how the burden and associated changes for this proposed rule have been accounted for during the transition process from paper to electronic in which the information is

currently submitted by electronic means through FURLS, FDA has developed

tables 5 and 6 of this document as follows:

TABLE 5.—REPORTING REQUIREMENTS

21 CFR Section/ OMB Control No. 0910–0387	Section of the 2007 Amendments/ OMB Control No. 0910–0625	21 CFR Section/ NPRM
Paper Format	Electronic Format	Electronic Format
Forms FDA 2891,2891a, and 2892	Form FDA 3673	Form FDA 3673
807.22(a) and 807.40	222	807.22(a)
807.22(b)	223	807.22(b)(3)
807.22(a) and 807.40	224	807.22(b)(1)
807.22(b)	224	807.22(a)
Not reported	224	807.21(b)
Not reported	224	807.21(c)

TABLE 6.—RECORDKEEPING REQUIREMENTS

21 CFR Section/ OMB Control No. 0910–0387	Section of the 2007 Amendments/ OMB Control No. 0910–0625	21 CFR Section/ NPRM
Paper Format	Electronic Format	Electronic Format
Forms FDA 2891,2891a, and 2892	Form FDA 3673	Form FDA 3673
Not reported	222	807.25(d)
807.31	223	807.26

In compliance with the PRA, the agency has submitted the revised information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding the information collection to OMB (see **DATES** and **ADDRESSES** sections of this document).

#### VIII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### IX. Proposed Effective Date

FDA proposes that any final rule based on this proposal become effective 90 days after its date of publication in the **Federal Register**.

#### X. Proposed Compliance Dates

The proposed rule does not affect self-executing statutory responsibilities. Those FDAAA provisions establishing registration and listing requirements that are self-executing must be complied with in accordance with the statute and do not depend on this proposed rule becoming final.

#### XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### XII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### XIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Bureau of Labor Statistics, May 2008, National Industry-Specific Occupational Employment and Wage Estimates, NAICS 339100—Medical Equipment and Supplies Manufacturing, Occupation (SOC code): (131041) [http://www.bls.gov/oes/current/naics4\\_339100.htm](http://www.bls.gov/oes/current/naics4_339100.htm).

2. Eastern Research Group memorandum from Cal Franz, Derek Singer, and John Eyraud to FDA, September 15, 2008.

3. Office of Management and Budget, Circular A–4, Regulatory Analysis, Washington, DC, 2003, <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

#### List of Subjects in 21 CFR Part 807

Imports, Medical devices, Reporting and Recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner

of Food and Drugs, it is proposed that 21 CFR part 807 be amended as follows:

**PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES**

1. The authority citation for 21 CFR part 807 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

2. Amend § 807.3 by:

- a. Adding “and” at the end of paragraph (e)(3);
- b. Removing “;and” at the end of paragraph (e)(4) and adding a period in its place;
- c. Removing paragraph (e)(5);
- d. Revising paragraph (i);
- e. Redesignating paragraphs (k) through (s) as paragraphs (l) through (t), respectively; and
- f. Adding a new paragraph (k) and adding paragraphs (u) through (y).

The revisions and additions read as follows:

**§ 807.3 Definitions.**

\* \* \* \* \*

(i) *Restricted device* means a device for which a requirement restricting sale, distribution, or use has been established by a regulation issued under section 520(e) of the act, by order as a condition of premarket approval under section 515(d)(1)(B)(ii) of the act, or by a performance standard issued in accordance with sections 514(a)(2)(B)(v) and 514(b) of the act.

\* \* \* \* \*

(k) *Product code* means the code used by FDA to identify the generic category of a device.

\* \* \* \* \*

(u) *Fiscal year* means the FDA fiscal year, which runs from October 1 through September 30.

(v) *FURLS* means the Food and Drug Administration’s Unified Registration and Listing System.

(w) *FDA premarket submission number* means the number assigned by FDA to a premarket device submission, such as a Premarket Approval Application (PMA); Investigational Device Exemption (IDE); Humanitarian Device Exemption (HDE); Investigational New Drug Application (IND); New Drug Application (NDA); or Premarket Notification (510(k)).

(x) *Importer* means, for purposes of this part, a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment’s device that is imported into the United States. An

importer does not include the consumer or patient who ultimately purchases, receives, or uses the device, unless the foreign establishment ships the device directly to the consumer or patient.

(y) *Person who imports or offers for import* means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States.

3. Revise § 807.20 to read as follows:

**§ 807.20 Who must register and submit a device list?**

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term “device” includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party;

(2) Manufactures a device, including an establishment that sterilizes or otherwise makes a device for or on behalf of a specifications developer or any other person;

(3) Repackages or relabels a device;

(4) Reprocesses a single use device that has previously been used on a patient;

(5) Acts as an initial importer as defined in § 807.3(g), except that initial importers are not required to provide device listings for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device.

However, the initial importer shall submit, for each such device, the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importer;

(6) Manufactures 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, e.g. blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the act.

(c) Registration and listing requirements shall not pertain to any person who acts as a wholesale distributor, as defined in § 807.3(t), and who does not manufacture, repack, process, or relabel a device.

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of § 807.26 remain applicable.

(e) Owners and operators of establishments that manufacture devices licensed under section 351 of the Public Health Service Act as well as licensed biological products used in the manufacture of a licensed device must register and list following the procedures set out in part 607 of this chapter, instead of the procedures for registration and listing contained in this part.

**§ 807.22 [Removed]**

4. Remove § 807.22.

**§ 807.21 [Redesignated as § 807.22]**

5. Redesignate § 807.21 as § 807.22.

6. Add new § 807.21 to subpart B to read as follows:

**§ 807.21 How to register establishments and list devices.**

(a) Owners or operators of establishments that are subject to the registration and listing requirements of this part must provide the following information to us using our electronic device registration and listing system, except as provided in paragraphs (b), (c), and (d) of this section:

(1) Initial establishment registration information as required by §§ 807.22(a) and 807.25;

(2) Updates to registration information as required by § 807.22(b) and 807.25;

(3) Initial device listing information as required by § 807.22(a), 807.25, and 807.28;

(4) Updates to device listing information as required by § 807.22(b), 807.25, and 807.28, including updates to reflect the discontinuance or resumption of the commercial distribution of a previously-listed device as specified at paragraphs (d) and (e) of § 807.28.

(b) If the information under § 807.21(a) cannot be submitted electronically, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants must send a letter to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Building 66, rm. 2621, Silver Spring, MD 20993-0002, that includes the following information:

(1) The name and address of the device establishment(s) to be registered, a contact person for the owner or operator of the establishment, and the telephone number at which that person can be reached. If the establishment has already registered in the past, the letter should also include the owner or operator number, registration number, and any listing numbers previously assigned by FDA for that establishment.

(2) Information about whether the company is an initial importer as defined in § 807.3(g) and, if so, whether it also conducts any other activities or operations relating to devices.

(3) A statement that use of the Internet is not reasonable for the person requesting the waiver, and an explanation of why such use is not reasonable. The statement must be signed by the owner or operator of the establishment, or by a person employed by the owner or operator who is authorized to make the declaration on behalf of the owner or operator.

(c) Those owners or operators who have obtained a waiver from filing registration and listing information electronically should refer to § 807.34 for information on how to submit such information by postal mail.

(d) When additional device listing information (e.g., copies of labeling or advertisements) is requested by FDA as described at § 807.26(e), such information may be submitted by postal mail or electronically by e-mail, but will not be submitted using the FDA electronic device registration and listing system.

7. Revise newly redesignated § 807.22 to read as follows:

**§ 807.22 Times for establishment registration and device listing.**

(a) *Initial registration and listing.* An owner or operator of an establishment who has not previously entered into an operation described in § 807.20(a) shall register within 30 days after entering into such an operation and submit device listing information at that time.

(b) *Registration and listing updates.* Owners or operators shall review and update all of their establishment registration and device listing information that is on file at FDA, documenting any changes that were not previously reported as follows:

(1) Annual registration for each fiscal year is required for all establishments. Annual registration shall take place during the period beginning on October 1 and ending on December 31 of each fiscal year;

(2) Updates to the registration information as described in § 807.25(b) shall be made within 30 days of any change to such information;

(3) Every fiscal year, during the period beginning on October 1 and ending on December 31, owners or operators shall review and update all of their device listing information that is on file at FDA, reporting any changes or deletions to listings and any new listings that were not previously reported. The accuracy of all information on file must be confirmed each year regardless of whether any changes were made to the owner or operator's list of devices; and

(4) Changes to listing information may also be made at other times, such as when a device is introduced into commercial distribution, when a change is made to a previously-listed device, or when a previously-listed device is removed from commercial distribution.

(c) Failure to submit any of the required information on time, as specified in paragraphs (a) and (b) of this section, will put the establishment in a "failed to register" or "failed to list" status as applicable. The establishment

will not be considered active and the establishment registration and device listing information will not appear on the FDA Web site until such time as the owner or operator submits and FDA processes the required information.

8. Revise § 807.25 to read as follows:

**§ 807.25 Information required for establishment registration and device listing.**

(a) All owners or operators that are subject to the registration and listing requirements of this part shall provide such information to us by using the FDA electronic device registration and listing system, unless granted a waiver from electronic submission in accordance with § 807.21(b). Electronic submissions of registration and listing information must comply with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30. Those owners or operators granted a waiver from electronic submission should refer to paragraphs (c) and (g) of this section and § 807.34 for instructions on how to submit device registration and listing information.

(b) Registration information required to be submitted includes: The name and mailing address of the device establishment; the Web site address of the device establishment, if any; the name, address, phone number, fax number, and e-mail address of the owner or operator; the name, address, phone number, fax number, and e-mail address of the establishment's official correspondent; and all trade names used by the establishment.

(c) Owners or operators who have been granted a waiver from electronic filing must submit the establishment registration information described in paragraph (b) of this section, except for the Web site and e-mail address information, in paper form using the procedures set forth in § 807.34.

(d) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment registered by the owner or operator and to furnish this information to FDA upon request.

(e) For each establishment, an official correspondent must be designated by the owner or operator to serve as a point of contact with FDA on matters relating to the registration of device establishments and the listing of device products. Each owner or operator shall also provide FDA with the name of a contact person at the owner or operator's offices who will be responsible for identifying the official correspondent for each establishment. The owner or operator contact person

will be the official correspondent in the event no one else has been properly designated. The official correspondent is responsible for:

- (1) Providing FDA with all required registration and listing information electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b) ;
- (2) Receiving all correspondence from FDA concerning registration and listing;
- (3) Supplying, when requested by FDA, the names of all officers, directors, and partners; and
- (4) Receiving communications from FDA by e-mail, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.
- (f) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the act.
- (g) Device listing information must be submitted to FDA electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b). Owners or operators who have been granted a waiver must submit the required device listing information, including information required by this paragraph, § 807.28, and any listing information requested by FDA under § 807.26(e), in paper form using the procedures set forth in § 807.34. The information required for each device listed includes:
  - (1) The current registration number and name of each establishment under the ownership and control of the owner or operator where the device is manufactured, repackaged, relabeled, or otherwise processed, or where specifications are developed.
  - (2) The product code for each device that is exempt from premarket notification and approval or which was in commercial distribution prior to May 28, 1976.
  - (3) The proprietary or brand name(s) under which each device is marketed.
  - (4) The FDA-assigned premarket submission number of the approved application, cleared premarket notification, or approved humanitarian device exemption for each device listed that is subject to sections 505, 510, 515, or 520 of the act, which includes devices that are not exempt from premarket notification and approval.
  - (5) Each activity or process that is conducted on or done to the device at each establishment, such as manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device

reprocessing, contract manufacturing, contract sterilizing, or manufacturing for export only.

#### **§ 807.26 [Removed and Reserved]**

9. Remove and reserve § 807.26.

#### **§ 807.31 [Redesignated as § 807.26]**

10. Redesignate § 807.31 as § 807.26.  
 11. Amend newly redesignated § 807.26 by adding paragraph (f) to read as follows:

#### **§ 807.26 Additional listing information.**

\* \* \* \* \*

(f) Labeling, advertisements, and other information to be submitted upon request in accordance with paragraph (e) of this section may be submitted by postal mail or electronically by e-mail, but will not be submitted using the FDA electronic device registration and listing system. Electronic submissions of such information must comply with part 11 of this chapter, except for the requirements in § 11.10 (a), (c) through (h), and (k), and the corresponding requirements in § 11.30. The information provided in electronic format must be in a form that we can process, review, and archive.

#### **§ 807.30 [Redesignated as § 807.28]**

12. Redesignate § 807.30 as § 807.28.  
 13. Revise newly redesignated § 807.28 to read as follows:

#### **§ 807.28 Updating device listing information.**

(a) Updating of device listing information is required when an additional establishment begins to engage in any of the activities described in § 807.3(d) with respect to a listed device, such as manufacturing, developing specifications, repackaging, relabeling, or otherwise processing the device. Updating of the listing is also required when an establishment begins performing another activity on or to the device, or ceases to perform an activity on or to the device that had previously been identified on the device listing.

(b) An owner or operator shall create a new device listing using the FDA electronic device registration and listing system:

- (1) When introducing into commercial distribution an exempt device identified with a product code that is not currently listed by the owner or operator; or
- (2) When introducing into commercial distribution a non-exempt device with an FDA premarket submission number that is not currently listed by the owner or operator.

(c) All device listings for foreign establishments must be submitted before the device may be imported or

offered for import into the United States.

(d) An owner or operator who discontinues commercial distribution of a device shall discontinue the device listing using the FDA electronic device registration and listing system. A device listing is considered discontinued if:

- (1) All devices under an exempt product code have been discontinued or
- (2) All devices associated with an FDA premarket submission number have been discontinued.

(e) If commercial distribution of a discontinued device is resumed, the owner or operator must reactivate the previously-discontinued listing using the electronic device registration and listing system. Any changes to the listing information for the product that is the subject of the listing such as a new establishment, new activity, or new proprietary name must be made using the electronic device registration and listing system at the time the listing is reactivated.

(f) FDA will assign one listing number for all devices exempt from premarket notification requirements under a single product code. For products not exempt from premarket notification requirements, a single listing number will be assigned by FDA for each FDA premarket submission number.

14. Add § 807.34 to subpart B to read as follows:

#### **§ 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.**

(a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25, (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Office of Compliance, Center for Devices and Radiological Health (HFZ-308), Food and Drug Administration, 10903 New Hampshire Ave., Building 66, room 3521, Silver Spring, MD 20993-0002.

(b) As specified in § 807.22(b)(1) and (b)(3), all owners or operators shall update their establishment registration and device listings annually during the period beginning on October 1 and ending on December 31 of each fiscal year.

(c) Failure to submit any of the required information on time, as specified in § 807.22(a) and (b), will put the establishment in a “failed to register” or “failed to list” status as applicable.

The establishment will not be considered active and the establishment registration and device listing information will not appear on the FDA Web site until the required information is submitted to and processed by FDA.

15. Amend § 807.35 by revising paragraphs (a) and (b) to read as follows:

**§ 807.35 Notification of registrant.**

(a) FDA will assign each device establishment a permanent registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by e-mail, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.

\* \* \* \* \*

16. Revise § 807.37 to read as follows:

**§ 807.37 Public availability of establishment registration and device listing information.**

Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the act and will be posted on the FDA Web site. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health (HFZ-308), Food and Drug Administration, 10903 New Hampshire Ave., Building 66, rm. 3521, Silver Spring, MD 20993-0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a

registration number or location of a registered establishment will be provided.

17. The heading of subpart C is revised to read as set forth below:

**Subpart C—Procedures for Foreign Device Establishments**

18. Amend § 807.40 by revising paragraphs (a) and (c) and by adding paragraph (d) to read as follows:

**§ 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.**

(a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register such establishment and list such devices using the FDA electronic device registration and listing system in conformance with the procedures in this section, § 807.41, and subpart B of this part. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of the Food and Drug Administration for matters relating to the registration of device establishments and the listing of device products.

\* \* \* \* \*

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter.

(d) The establishment registration and device listing information shall be in the English language.

19. Add § 807.41 to subpart C to read as follows:

**§ 807.41 Identification of importers and persons who import or offer for import.**

(a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, e-mail address, and registration number, if any has been assigned, of any importer (defined in § 807.3(x)) of the establishment's devices that is known to the foreign establishment. The foreign establishment must also specify which

of the establishment's listed products each importer receives from the foreign establishment.

(b) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, e-mail address, and registration number, if any has been assigned, of each person who imports or offers for import the establishment's devices into the United States. The term "person who imports or offers for import," which is defined in § 807.3(y), includes agents, brokers, or other parties used by the foreign establishment to facilitate the import of its device into the United States.

(c) For each individual or organization identified by the foreign establishment under paragraphs (a) and (b) of this section, the foreign establishment must submit to FDA electronically the current FDA premarket submission number (e.g., PMA, 510(k), HDE, NDA) and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

Dated: March 22, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

[Docket No. DEA-333]

**Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV; Announcement of Hearing**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Notice of hearing on proposed rulemaking.

**SUMMARY:** This is notice that the Drug Enforcement Administration (DEA) will hold a hearing with respect to the proposed placement of carisoprodol in schedule IV of the Controlled Substances Act (21 U.S.C. 801, *et seq.*). The control of carisoprodol was initially proposed in a Notice of Proposed Rulemaking published in the **Federal**