

§ 807.21

21 CFR Ch. I (4-1-08 Edition)

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 for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a 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.

(3) Repackages or relabels a device;

(4) Acts as an initial importer; or

(5) Manufactures components or accessories which 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) No registration or listing fee is required. 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:

(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.

(3) Acts as a wholesale distributor, as defined in §807.3(s), and who does not manufacture, repackage, 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 §807.31 remain applicable.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 5466, Jan. 19, 2001; 66 FR 59160, Nov. 27, 2001]

§ 807.21 Times for establishment registration and device listing.

(a) An owner or operator of an establishment who has not previously entered into an operation defined in §807.20 shall register within 30 days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within 30 days after receiving registration forms from FDA. FDA will mail form FDA-2891a to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows:

First letter of owner or operator name	Date FDA will mail forms
A, B, C, D, E	March.
F, G, H, I, J, K, L, M	June.
N, O, P, Q, R	August.
S, T, U, V, W, X, Y, Z	November.

(b) Owners or operators of all registered establishments shall update their device listing information every June and December or, at their discretion, at the time the change occurs.

[58 FR 46522, Sept. 1, 1993]

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on Form FDA-2891 (Initial Registration of Device Establishment). Forms are available upon request from the Office of Compliance,

Center for Devices and Radiological Health (HFZ-308), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-4015, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDA-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FDA-2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FDA-2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FDA-2892, tapes for computer input or hard copy computer output may be submitted if equivalent in all elements of information as specified in form FDA-2892. All formats proposed for use in lieu of form FDA-2892 require initial review and approval by the Food and Drug Administration.”

(c) The listing obligations of the initial importer are satisfied as follows:

(1) The initial importer is not required to submit a form FDA-2892 for those devices for which such initial importer did not initiate or develop the specifications for the device or repackaging or relabel the device. However, the initial importer shall submit, for each 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 importers; and

(2) The initial importer shall update the information required by paragraphs (c)(1) of this section at the intervals specified in § 807.30.

[43 FR 37997, Aug. 25, 1978, as amended at 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 69 FR 11311, Mar. 10, 2004; 69 FR 18473, Apr. 8, 2004; 69 FR 25489, May 7, 2004]

§ 807.25 Information required or requested for establishment registration and device listing.

(a) Form FDA-2891 and Form FDA-2891(a) are the approved forms for initially providing the information required by the act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including post office code, all trade names used by the establishment, and the business trading name of the owner or operator of such establishment.

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing devices.

(c) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment he registers and to furnish this information to the Food and Drug Administration upon request.

(d) Each owner or operator shall provide the name of an official correspondent who will serve as a point of contact between the Food and Drug Administration and the establishment for matters relating to the registration of device establishments and the listing of device products. All future correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to this official correspondent. In the event no person is designated by the owner or operator, the owner or operator of the establishment will be the official correspondent.

(e) 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.

(f) Form FD-2892 is the approved form for providing the device listing