

§ 807.21

device within the meaning of section 201(h) of the act.

(c) Distributors of domestic or imported devices must register and fulfill their listing obligations as described in §807.22(c) of this part. Distributors with multiple sites may submit one registration for all sites or submit a registration for each site. If a multisite distributor chooses to file one registration, the registration must be from the principal business establishment which maintains the MDR complaint files.

(d) 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.

[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]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in §807.20, paragraph (a)(6) was stayed indefinitely.

**§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-307), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDD-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 updates shall be on form FD-2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FD-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 FD-2892, tapes for computer input or hard copy computer output may be submitted if equivalent in all elements of information as specified in form FD-2892. All formats proposed for use in lieu of form FD-2892 require initial review and approval by the Food and Drug Administration.

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

(1) The distributor is not required to submit a form FDA-2892 for those devices for which such distributor did not