

§ 807.26

21 CFR Ch. I (4-1-01 Edition)

the device listing package, an appropriate classification name for the device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37998, Aug. 25, 1978; 58 FR 46523, Sept. 1, 1993; 64 FR 404, Jan. 5, 1999]

§ 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FD-2891(a). This information shall be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

§ 807.30 Updating device listing information.

(a) Form FD-2892 shall be used to update device listing information. The preprinted original document number of each form FD-2892 on which the device was initially listed shall appear in block 2 on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

(1) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FD-2892 containing all the information required by § 807.25(f).

(2) If an owner or operator discontinues commercial distribution of all devices in the same device class, i.e., with the same classification name, the owner or operator must submit form FD-2892 containing the original document number of the form FD-2892 on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or

operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued device.

(3) If commercial distribution of a discontinued device identified on a form FD-2892 filed under paragraph (b)(2) of this section is resumed, the owner or operator must submit on form FD-2892 a notice of resumption containing: the original document number of the form initially used to list that device class, the reason for submission, date of resumption, and all other information required by § 807.25(f).

(4) If one or more classification names for a previously listed device with multiple classification names has been added or deleted, the owner or operator must supply the original document number from the form FD-2892 on which the device was initially listed and a supplemental sheet identifying the names of any new or deleted classification names.

(5) Other changes to information on form FD-2892 will be updated as follows:

(i) Whenever a change occurs only in the owner or operator name (block 6) or number (block 7), e.g., whenever one company's device line is purchased by another owner or operator, it will not be necessary to supply a separate form FD-2892 for each device. In such cases, the new owner or operator must follow the procedures in § 807.26 and submit a letter informing the Food and Drug Administration of the original document number from form FD-2892 on which each device was initially listed for those devices affected by the change in ownership.

(ii) The owner or operator must also submit update information whenever changes occur to the responses to the questions in blocks 12, 12a, 13, 13a, and 14 on form FD-2892, or whenever establishment registration numbers, establishment names, and/or activities are added to or deleted from blocks 15, 16, and 17 of form FD-2892. The owner or operator must supply the original document number from the form FD-2892 on which the device was initially listed, the reason for submission, and all other information required by § 807.25(f).