

the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:

(1) For each device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device;

(2) For each restricted device, a copy of all labeling and advertisements for the device;

(3) For each device that is neither restricted nor subject to section 514 or 515 of the act, a copy of all labels, package inserts, and a representative sampling of any other labeling.

(b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing.

(c) Each owner or operator may discard labeling and advertisements from the historical file 3 years after the date of the last shipment of a discontinued device by an owner or operator.

(d) Location of the file:

(1) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner.

(2) The contents of the historical file may be physically located in more than one place in the establishment or in more than one establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Food and Drug Administration with a letter authorizing the establishment outside its control to maintain the historical file.

(3) A copy of the certification and disclosure statements as required by part 54 of this chapter shall be retained and physically located at the establishment maintaining the historical file.

(e) Each owner or operator shall be prepared to submit to the Food and Drug Administration, only upon spe-

cific request, the following information:

(1) For a device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device.

(2) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where feasible, be accompanied by an explanation of the basis for such request.

(3) For a device that is neither a restricted device, nor subject to section 514 or 515 of the act, the label and package insert for the device and a representative sampling of any other labeling for the device.

(4) For a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.

(5) For a particular device, a statement of the basis upon which the registrant has determined the device is not a restricted device.

(6) For a particular device, a statement of the basis for determining that the product is a device rather than a drug.

(7) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

[43 FR 37999, Aug. 25, 1978, as amended at 51 FR 33033, Sept. 18, 1986; 63 FR 5253, Feb. 2, 1998]

§ 807.35 Notification of registrant.

(a) The Commissioner will provide to the official correspondent, at the address listed on the form, a validated copy of Form FD-2891 or Form FD-2891(a) (whichever is applicable) as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

(b) Owners and operators of device establishments who also manufacture or process blood or drug products at the same establishment shall also register with the Center for Biologics Evaluation and Research and Center for Drug

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Evaluation and Research, as appropriate. Blood products shall be listed with the Center for Biologics Evaluation and Research, Food and Drug Administration, pursuant to part 607 of this chapter; drug products shall be listed with the Center for Drug Evaluation and Research, Food and Drug Administration, pursuant to part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37999, Aug. 25, 1978; 53 FR 11252, Apr. 6, 1988]

§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FD-2891 and FD-2891a filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850. 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 office. Upon request, verification of registration number or location of a registered establishment will be provided.

(b)(1) The following information filed under the device listing requirements will be available for public disclosure:

- (i) Each form FD-2892 submitted;
- (ii) All labels submitted;
- (iii) All labeling submitted;
- (iv) All advertisements submitted;

(v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Center for Devices and Radiological

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Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850.

(3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with part 20 of this chapter.

[43 FR 37999, Aug. 25, 1978, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Registration Procedures for Foreign Device Establishments

§ 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 and list such devices in conformance with the requirements in subpart B of this part unless the device enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce. 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.

(b) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its