(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Certify in accordance with § 803.57;

(4) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(5) Maintain complaint files in accordance with § 803.18; and

(6) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

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

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

3. Section 807.3 is amended by adding new paragraph (r) to read as follows:

§ 807.3 Definitions.

* * * * *

(r) *U.S.-designated agent* means the person, residing in the United States, designated and authorized by the owner or operator of a foreign manufacturer who exports devices into the United States and is responsible for:

(1) Submitting MDR reports,

(2) Submitting annual certifications,

(3) Acting as the official correspondent,

(4) Submitting registration information,

(5) Submitting device listing information, and

(6) Submitting premarket notifications on behalf of the foreign manufacturer.

4. Section 807.20 is amended by adding new paragraph (a)(6) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) * * *

(6) Acts as the U.S.-designated agent as defined in § 807.3(r).

* * * * *

5. Section 807.22 is amended by revising paragraph (a) to read as follows:

§ 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.

* * * * *

6. Section 807.40 is revised to read as follows:

§ 807.40 Establishment registration and device listing for U.S. agents of foreign manufacturers of devices.

(a) Each foreign device manufacturer who exports devices into the United States shall designate a person as their U.S.-designated agent, who is responsible for:

(1) Submitting MDR reports,

(2) Submitting annual certifications,

(3) Acting as the official correspondent,

(4) Submitting registration information,

(5) Submitting device listing information, and

(6) Submitting premarket notifications.

(b) The foreign manufacturer shall provide FDA with a statement of authorization for their U.S.-designate to perform MDR reporting duties under part 803 of this chapter, and to register, list, and submit premarket notifications under this part. The foreign manufacturer must provide this statement of authorization along with the name, address, and telephone number of the person initially designated, or any subsequent person designated as the U.S.-designated agent, within 5 days of the initial or subsequent designation. Information shall be sent to the Center for Devices and Radiological Health, Medical Device Reporting, Food and Drug Administration, P.O. Box 3002, Rockville, MD 20847–3002.

(c) The U.S.-designated agent of a foreign device manufacturer that exports devices into the United States is required to register the foreign manufacturer's establishments or places of business, and to list the foreign manufacturer's devices, in accordance with subpart B of this part, unless exempt under subpart D of this part, and to submit premarket notifications in accordance with subpart E of this part. The information submitted shall be in the English language.

Dated: October 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–29906 Filed 12–8–95; 8:45 am]

BILLING CODE 4160–01–P

21 CFR Part 5

Delegations of Authority; Medical Device Reporting Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to redelegate to certain officials in the Center for Devices and Radiological Health (CDRH) authorities relating to medical device reporting procedures.

EFFECTIVE DATE: December 11, 1995.

FOR FURTHER INFORMATION CONTACT:

Kerry G. Rothschild, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, or

Ellen R. Rawlings, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority under part 5 (21 CFR part 5) by adding new § 5.98 *Authority relating to medical device reporting procedures*. In conjunction with CDRH's issuance of a medical device reporting final rule under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), the Commissioner of Food and Drugs (the Commissioner) has decided to delegate to certain officials in CDRH the authority to approve electronic reporting under 21 CFR 803.14, to request the submission of additional information under 21 CFR 803.15, and to grant or revoke exemptions and variances from reporting requirements under 21 CFR 803.19. Delegation of these authorities to the directors and deputy directors of the Office of the Director and the Office of Surveillance and Biometrics, CDRH,