DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 804, and 807

[Docket No. 91N–0295]

RIN 0910–AA09

Medical Devices; Medical Device Distributor and Manufacturer Reporting; Certification, Registration, Listing, and Premarket Notification Submission; Stay of Effective Date; Revocation of Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: In response to numerous requests for the Food and Drug Administration (FDA) to consider further comments concerning medical device reporting (MDR) certification and U.S. designated agent requirements, FDA is staying the effective date of these two specific provisions of the adverse event reporting final rule that was published in the Federal Register of December 11, 1995. Specifically, these provisions relate to manufacturer certification and U.S. designated agent requirements. In addition, for consistency purposes, FDA is revoking the distributor reporting certification requirement that went into effect on May 28, 1992.

EFFECTIVE DATE: July 23, 1996.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 11, 1995 (60 FR 63578), FDA published a final rule amending parts 803 and 807 (21 CFR parts 803 and 807) to require medical device manufacturers, including U.S. designated agents of foreign manufacturers, to report adverse events related to medical devices under a uniform reporting system (hereinafter referred to as the December 1995 final rule). This rule also required U.S. designated agents to register, list, and submit premarket notifications on behalf of foreign manufacturers. The effective date of this rule was to be April 11, 1996. On April 11, 1996 (61 FR 16043), FDA extended the effective date to July 31, 1996.

Earlier, in the Federal Register of September 1, 1993 (58 FR 46514), FDA published a notice announcing that the distributor reporting requirements, including certification, that were published as a tentative final rule on November 26, 1991, became effective by operation of law on May 28, 1992.

After issuing the December 1995 final rule, FDA received numerous requests for reconsideration of the certification requirements and for reconsideration of issues relating to U.S. designated agent requirements. These comments led FDA to meet with the Health Industry Manufacturers Association (HIMA) and several industry representatives on April 19, May 23, and June 13, 1996. During these meetings, issues concerning industry burdens and procedures relating to the certification and U.S. designated agent requirements were put forth that had previously not been fully considered.

Section 519(d) of the act (21 U.S.C. 360i(d)) states that each manufacturer and distributor required to make reports under section 519(a) (21 U.S.C. 360i(a)) of the act must submit annual statements certifying the number of reports that were filed or that no reports were filed during the previous 12-month period. The certification regulations for manufacturers and distributors require that the certification include the number of MDR's filed during the previous 12-month period and that all MDR reportable events have been submitted (§§ 803.57 and 804.30 (21 CFR 804.30)). FDA required the certification that all MDR reportable events were filed on the basis of legislative history citing the General Accounting Office report recommending that certification state that the reporter ''filed a specific number of reports * * * and that the firm received or became aware of information concerning only these events.'' (H. Rept. 808, 101st Cong., 2d sess., 23 (1990).) FDA, in response to comments asking who should certify for manufacturers, also required in the December 1995 final rule that the certifier must be the president, chief executive officer, U.S. designated agent of a foreign manufacturer, or other official most directly responsible for the firm's operations.

After the final rule was issued, FDA received comments taking the position that the certifier may more appropriately be a person with more direct involvement with the reporting requirements. Comments also objected to requiring that the reporter certify all reportable events have been filed on the basis that such a requirement was not specifically required in the act, and that potential liability would be created.

The December 1995 final rule also required that foreign firms identify a U.S. designated agent who would be responsible for the foreign firm's MDR reporting requirements, as well as the foreign manufacturer's registration listing and premarket notification submissions. After issuing the December 1995 final rule, FDA received comments from industry objecting to these requirements as being unduly burdensome. In response to these comments, FDA is publishing a proposed rule, elsewhere in this issue of the Federal Register, addressing the certification and U.S. designated agent issues. FDA intends that the requirements relating to distributor and manufacturer certification, and to U.S. designated agents, will not be in effect until at least 75 days after the date of publication in the Federal Register of a new final rule.

The Administrative Procedure Act (Pub. L. 79–404) and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereof in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(8); § 10.40(e)(1) (21 CFR 10.40 (e)(1)).) FDA finds that there is good cause for dispensing with notice and comment procedures to stay the effective date of the manufacturer certification and U.S. designated agent reporting provisions, (§§ 803.3(n)(4), 803.57, 803.58, 807.3(r), 807.20(a)(6), and 807.40) and for revoking the certification requirements for distributors (§ 804.30) because such notice and comment procedures are impracticable and contrary to the public interest.

Notice and comment rulemaking on the postponement of manufacturer certification and U.S.designated agent requirements is impracticable. FDA was not aware of a number of significant issues relating to these requirements until after publication of the December 1995 final rule. Since that time, FDA has had numerous meetings with HIMA and industry representatives and internal meetings to decide the best approach to understand and resolve issues concerning the rule. The last meeting with HIMA and industry representatives occurred on June 13, 1996. Without the issuance of a stay under good cause procedures, the certification and U.S. designated agent requirements would become effective on July 31, 1996.

In addition, notice and comment rulemaking, in this instance, on the stay of the present certification requirements would be contrary to the public interest. Because there is not enough time to allow notice and comment on the issue

of staying the effective date before it occurs, the certification and U.S. designated agent requirements would be in effect only for the interim period between the effective date of the final manufacturer rule, July 31, 1996, and the date the agency expects that these provisions, after issuance of a reproposed rule, would be revised and become final a second time. This result would cause industry to implement costly certification and U.S. designated agent procedures and contractual arrangements that would most likely have to be changed with additional cost after these requirements are reproposed and refinalized.

It is also against the public interest to have a certification requirement in effect for distributors, while not having such a requirement in effect for manufacturers. The MDR system is intended to operate as a uniform reporting system where user facilities, distributors, and manufacturers efficiently share, forward, and provide complementary information on the same adverse events. Having a system whereby distributors certify reports and manufacturers do not certify reports would hinder the uniformity of this program and result in regulatory confusion.

For all the reasons stated above, FDA concludes, under 5 U.S.C. 553(b)(8) and § 10.40(e)(1), that there is good cause for staying the effective date of the certification and U.S. designated agent provisions of the December 1995 final rule and for revoking the distributor certification requirements of the May 28, 1992 rule.

Foreign manufacturers have a responsibility for compliance with all medical device reporting requirements which will not be affected by the stay of the effective date of the U.S. designated agent requirements. This is because the December 1995 final rule contained a significant change regarding foreign manufacturers. The original medical device reporting regulation that became effective December 13, 1984, defined a manufacturer who was required to submit MDR reports as any person who is required to register under part 807. Because foreign manufacturers are not required to register, the December 1984 regulation did not apply to them. The revised December 1995 final rule, however, no longer defines a manufacturer who is required to report adverse events as a person who is required to register under part 807. Rather, under § 803.3(n) of the December 1995 final rule, a manufacturer means any person who manufactures, prepares, propagates compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. Accordingly, foreign manufacturers clearly fit within the definition of manufacturers who are required to submit MDR's under the December 1995 final rule. This means that, on July 31, 1996, foreign manufacturers will be fully subject to the same requirements of part 803 applicable to all domestic manufacturers. This includes, but is not limited to, the requirements for written procedures (§ 803.17), MDR event files (§ 803.18), individual adverse event reports (§§ 803.50 and 803.52), 5-day reports (§ 803.53), baseline reports (§ 803.55), and supplemental reports (§ 803.56). In addition, existing regulations will remain in effect pending the stay that permits foreign manufacturers to register (§ 807.40(a)) and submit premarket notifications (§ 807.81), and require them to list their devices (§ 807.40(b)).

List of Subjects

21 CFR parts 803 and 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 803, 804, and 807 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

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

1. In the revision of part 803 and the amendments to part 807 which were published at 60 FR 63578 (December 11, 1995), the effective date of which was extended until July 31, 1996, at 61 FR 16043 (April 11, 1996), the following provisions are stayed until further notice:

A. §§ 803.3(n)(4), 803.57, and 803.58.

B. The addition of § 807.3(r) and 807.20(a)(6); and

C. The revision of § 807.40.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

2. The authority citation for 21 CFR part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

§ 804.30 [Removed]

3. Section 804.30 is removed.

Dated: July 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–18700 Filed 7–19–96; 2:26 pm]

BILLING CODE 4160–01–F