DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803 and 804

[Docket No. 96N–0241]

RIN 0910–AA09

Medical Devices; Reporting; Certification and U.S. Designated Agents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its regulations for medical device manufacturer certification, and to issue conforming certification requirements for distributors. FDA is also announcing its intent to reconsider the requirement for foreign manufacturers to appoint a U.S. designated agent to perform certain duties under the adverse event reporting final rule that was published in the Federal Register of December 11, 1995. FDA is taking this action in response to comments from industry raising concerns that have not been addressed previously. Elsewhere in this issue of the Federal Register, FDA is announcing a stay of the effective date of the manufacturer certification and U.S. designated agent provisions and the revocation of the May 28, 1992, distributor certification provisions. This proposed rule will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended uses while reducing the regulatory burden on reporting entities.

DATES: Submit written comments by October 7, 1996. FDA intends that any final rule based on this proposal become effective 75 days after publication of the final rule in the Federal Register.

Submit written comments on the collection of information requirements by August 22, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

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.

I. Background

SUPPLEMENTARY INFORMATION: In the Federal Register of December 11, 1995 (60 FR 63578), FDA published a final rule (parts 803 and 807 (21 CFR parts 803 and 807)) requiring medical device user facilities and manufacturers to report adverse events related to medical devices under a uniform reporting system (hereinafter referred to as the December 1995 final rule). The December 1995 final rule was scheduled to go into effect on April 11, 1996. On April 11, 1996 (61 FR 16043), FDA announced that OMB had approved the information collection requirements in the final rule; FDA also announced an extension of the effective date of the final rule to July 31, 1996. On May 28, 1992, a distributor adverse event reporting rule became final. This rule went into effect by operation of statute without the benefit of notice and comment.

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

To allow further consideration of these issues before implementation, elsewhere in this issue of the Federal Register, FDA is publishing a final rule staying the effective date of the manufacturer certification and U.S. designated agent requirements until the agency issues a new final rule addressing these issues. This final rule also revokes the May 28, 1992, distributor certification provisions to provide uniform manufacturer and distributor certification requirements.

A. Section 803.57—Annual Certification

Section 519(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(d)) (the act) provides that each manufacturer, importer, and distributor shall certify that it did file a certain number of medical device reports (MDR's) in the previous 12 months or it did not file any MDR reports. The final rule (§ 803.57) required manufacturers through their president, chief executive officer (C.E.O.), U.S. designated agent of a foreign manufacturer, or other official most directly responsible for the firm's operations, to certify that they filed MDR's for all reportable events required under the rule for the previous 12 months and a numerical summary of MDR's that they submitted, or that they did not receive any reportable events during the reporting period.

Industry representatives objected to the corporate status of the person required to certify, as well as the content of the certification statement itself. Industry representatives objected to requiring the C.E.O. or president to certify, because, especially in a large company, that person may not be familiar with the details of the MDR reporting program. Industry representatives also objected to the requirement that they certify that they filed reports for all reportable events during the reporting period. Industry representatives objected that this requirement was not supported by the language of section 519(d) of the act and objected to potential liability that may arise from certification that all reportable events had been submitted, if there were unintentional reporting mistakes.

In the December 1995 final rule, FDA required the certification that all MDR reportable events were filed on the basis of the statute's legislative history. The legislative history of section 519(d) of the act states that Congress included this provision on the recommendation of the General Accounting Office (GAO) as an important means of increasing the effectiveness of the MDR system. (See H. Rept. 808, 101st Congress, 2d sess. 23, (1990); S. Rept. 513, 101st Congress, 2d sess. 26, (1990)). The GAO report noted that certain information indicated that a third of the establishments inspected were not even aware that the MDR reporting requirements existed (GAO/PEMD–89–10, ''FDA's Implementation of the Medical Device Reporting Regulation,'' p. 4). The GAO report recommended certification to ensure that all manufacturers and importers be made aware of their obligation to submit MDR's and to identify those firms that were not aware of their obligation (id. at pp. 5 and 69). The legislative history of section 519(d) of the act also cites the GAO report recommendation that the certification state that the reporter filed a specific number of reports and that the firm received or became aware of only these reports (H. Rept. 808, 101st Congress, 2d sess. 23).

FDA believes that its regulation implementing the certification requirements was within the scope of the statutory authority provided in section 519(d) of the act. FDA, however, in response to the comments objecting to the person required to certify and to the content of the certification, has reexamined the certification requirement and believes that the regulation may be revised in a manner that will address the main concerns raised about the regulation and still meet the intent of section 519(d) of the act that will improve MDR efficiency by making firms aware of their reporting obligations under MDR.

FDA designated in the December 1995 final rule that the certifier must be the president, C.E.O., U.S. designated agent, or other official most directly responsible for the firm's operations, in response to a comment to the tentative final rule (56 FR 60024, November 26, 1991) requesting FDA to identify who should certify. FDA now believes, however, based on subsequent comments received, that it may be appropriate for someone other than the president or chief executive officer to sign the certification statement. FDA believes that the proposal suggested by the comments to place this particular responsibility of certification with the same individual in whom the company has already vested overall responsibility for implementing and overseeing its MDR program may be more appropriate than requiring certification by the president or C.E.O. FDA, therefore, is proposing to revise § 803.57 to provide that the manufacturer shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's medical device reporting system.

This proposal also provides that, based upon its organizational structure, a firm may designate more than one certifying official, each of whom would sign a certification statement for his or her identified organizational component or site. This provision is designed to provide needed flexibility to large companies with more than one operating division or medical device reporting site.

Regarding the content of the certification, FDA is proposing to amend § 803.57 to require that the individual certifying for the firm state that: (1) He/she has read the requirements of the MDR regulation, (2) the firm has established a system to implement medical device reporting; and (3) following the procedures of its medical device reporting system, the firm submitted a specified number of reports, or no reports, during the certification period.

FDA believes that this certification statement is a reasonable application of the intent of section 519(d) of the act. The legislative intent is to improve compliance with the MDR reporting requirements by making responsible persons within medical device companies fully aware of the MDR reporting requirements. This intent may be reasonably accomplished by requiring a responsible company official to certify that: (1) He/she has read the MDR regulation, (2) the company has put in place a system to implement those regulations, and (3) a specified number of MDR reports were submitted during the previous year as a result of its implementation system.

Under proposed § 803.57(a), the dates of certification would remain the same as the December 1995 final rule, i.e., the date of the firm's annual registration. FDA intends that the first certification statement would be due with the first annual registration due at least 6 months after the effective date of the final rule. For example, if the final rule were to become effective in March 1997, the first group of certifications would be due with annual registrations due in September 1997 and would cover a 6-month period. The next group of annual certifications would be due in December 1997 and would cover a 9-month period. Annual certifications due in April 1998 or later would cover a 12-month period. Foreign manufacturers would be required to submit their certification with the annual registration, if they voluntarily register, or in accordance with the schedule in § 807.21(a).

B. Section 803.58—Foreign Manufacturers

Section 803.58 of the December 1995 final rule required that foreign manufacturers designate a U.S. agent to be responsible for reporting under part 803. U.S. designated agents were to be responsible for: (1) Reporting to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56; (2) conducting, or obtaining from the foreign manufacturer, the necessary information regarding the investigation and evaluation of the event under the requirements of § 803.50; (3) certifying in accordance with § 803.57; (4) forwarding MDR complaints to the foreign manufacturer and maintaining documentation of this requirement; (5) maintaining complaint files in accordance with § 803.18; and (6) registering, listing, and submitting premarket notifications in accordance with part 807.

After the issuance of the December 1995 final rule, manufacturers who began to implement arrangements with U.S. designated agents stated that it was difficult to find individuals willing to take on the duties of a U.S. designated agent and that fees were high for those willing to take on the duties. Manufacturers noted particular concern about the appropriateness of a U.S. designated agent providing certifications related to MDR's and premarket notification requirements because they believed that the U.S. designated agent may not be able to accurately provide such certifications. Moreover, the potential liability associated with certification responsibilities greatly increased the cost of U.S. designated agent services.

In addition to the concerns discussed previously, many other issues relating to the implementation and scope of U.S. designated agent requirements were raised for the first time after the December 1995 final rule. After further internal discussions, FDA decided to stay the effective date of these requirements, as noted elsewhere in this issue of the Federal Register, until further notice and comment proceedings and the issuance of a new rule.

In the interim, 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 MDR regulation that became effective December 13, 1984, applied only to manufacturers that were required to register under part 807. Because foreign manufacturers are not required to register, the 1984 rule did not apply to them. The December 1995 final rule, however, applies to manufacturers regardless of whether they are 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. Therefore, on July 31, 1996, foreign manufacturers will be fully subject to the same requirements of part 803 applicable to 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), five-day reports (§ 803.53), baseline reports (§ 803.55), and supplemental reports (§ 803.56).

The stayed provisions for U.S. designated agents would have required that these functions be performed by a U.S. designated agent on behalf of the foreign firm. Because FDA is staying the effective date of the U.S. designated agent requirement, the full responsibility for reporting is now the obligation of the foreign manufacturer. Beginning July 31, 1996, foreign manufacturers are required to submit MDR reports directly to FDA (except for certification). In addition, existing registration, listing, and premarket notification regulations, which will remain in effect during the stay, permit foreign manufacturers to register (§ 807.40(a)) and submit premarket notifications (§ 807.81) and require them to list their devices. (§ 807.40(b)).

FDA is reconsidering the duties of a U.S. designated agent. As noted in the preamble to the December 1995 final rule, FDA intends to issue a proposed rule to revoke the reporting requirements for distributors, including importers, (part 804 (21 CFR part 804)) and replace them with requirements consistent with the new manufacturer and user facility reporting requirements under part 803. Because importers may be able to play a role, in whole or in part, that was assigned to the U.S. designated agent in the December 1995 final rule, FDA believes that it would be appropriate to address the issue of U.S. designated agents at the same time the agency reproposes requirements for distributors and importers generally.

FDA included the U.S. designated agent requirement in the December 1995 final rule in order to assure that foreign and domestic manufacturers are treated equally and that FDA has access to the same information it has from domestic manufacturers that will enable the agency to protect the public health. To this end, FDA listed certain duties in the December 1995 final rule that a U.S. designated agent would be required to perform as described above. FDA solicits comments on who may best perform these duties and specifically seeks comments on the following points:

1. What person is best situated to perform the following duties that, in the December 1995 final rule, were assigned to the U.S. designated agent on behalf of the foreign manufacturer: (1) Reporting to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56; (2) conducting, or obtaining from the foreign manufacturer the necessary information regarding the investigation and evaluation of the event under the requirements of § 803.50; (3) certifying in accordance with § 803.57; (4) forwarding MDR complaints to the foreign manufacturer and maintaining documentation of this requirement; (5) maintaining complaint files in accordance with § 803.18; and (6) registering, listing, and submitting premarket notifications in accordance with part 807?

2. Should FDA require a foreign manufacturer to designate a U.S. agent to fulfill the role of an ''official correspondent'' with FDA regarding MDR reporting and other regulatory issues (e.g., product listing)? The intent of this function would be to ensure that FDA can easily contact foreign firms on MDR issues and communicate in English with them, particularly on urgent public health matters.

3. Should FDA require foreign manufacturers to designate a U.S. agent for the purpose of fulfilling their substantive U.S. MDR obligations regarding complaint investigations, reporting, and maintenance of MDR files? The intent of this function would be for FDA to be able to monitor MDR compliance of foreign firms without conducting a costly overseas inspection.

4. Can either of these functions readily be carried out by importers, or by other means, so that foreign manufacturers would not be required to enter into contractual arrangements with new entities?

5. How can these functions be carried out efficiently by foreign manufacturers who distribute devices into the United States by multiple importers, and how can FDA be routinely informed of all importers of a firm annually or on an as needed basis?

Notwithstanding FDA's intent to repropose these requirements, the agency has already tentatively concluded that it should propose that two aspects of the U.S. designated agent regulations be deleted. The first is the requirement for U.S. designated agents to issue the annual certification required under § 803.57. Upon reconsideration, FDA believes it is more appropriate for the foreign manufacturer to issue this certification as proposed in this rule. The other is the requirement for foreign manufacturers to submit premarket notifications (510(k)'s) through U.S. designated agents. Although the agency had hoped this provision would help resolve 510(k) ownership issues regarding foreign manufacturers, FDA is persuaded that the costs imposed by this requirement are not likely to outweigh the possible benefits. FDA solicits comment on its intent to propose to delete these two parts of the U.S. designated agent regulations.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the economic impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 22601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity. The agency believes that the proposed rule is consistent with the principles set out in the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. The proposed rule would apply to all medical device manufacturers and distributors whose devices are sold in the United States. The proposed rule would relieve two regulatory burdens. It would allow the certification statement to be signed by the person most familiar with the MDR program, not necessarily the president or C.E.O. It also changes the certification statement to minimize the possibility of liability as a result of an unintended mistake in reporting. Therefore, under the Regulatory Flexibility Act, 5 U.S.C. 2605(b), the Commissioner of Food and Drugs certifies that the proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collections are shown below along with an estimate of the annual record keeping and periodic reporting burden. Included in the estimate is the time for reviewing

instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Reporting and record keeping requirements for user facilities, distributors, and manufacturers of medical devices under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992 (General Requirements).

Description: This regulation proposes to amend regulations regarding device manufacturer and distributor reporting of deaths, serious injuries, and certain malfunctions related to medical devices. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on reporting entities. The rule amends information collection requirements which have been approved under OMB no. 0910–0059.

Description of Respondents: Businesses or other for profit organizations, nonprofit organizations, Federal, State, and local governments.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.57	12,000	1	12,000	1	12,000
804.30	8,200	1	8,200	1	8,200
Total	20,200		20,000		20,200

There are no capital or operating and maintenance costs expected as a result of this proposal.

Under OMB information collection no. 0910–0059, which expires on February 28, 1999, a total of 187,610 burden hours were approved for collection of information requirements in the December 11, 1995, final rule (60 FR 63578) on medical device user facility and manufacturer reporting, certification and registration. The 12,000 burden hours reported above in Table 1 for § 803.57 were included in that approval and therefore do not affect the total number of approved burden hours. However, the 8,200 burden hours reported in Table 1 for § 804.30 have not previously been considered in an information collection submission to OMB, and do represent an increase in the burden. Therefore, this proposed rule would add 8,200 hours to the existing approved burden and would result in a proposed total annual information collection burden of 195,810 hours (187,610 + 8,200 = 195,810).

Therefore, the agency solicits public comments on the revised information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of the proposed rule amending parts 803 and 804 to OMB for its review of the revised information collection requirements. Other organizations and individuals interested in submitting comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. Written comments on the information collections should be submitted by August 22, 1996.

List of Subjects in 21 CFR Parts 803 and 804

Imports, Medical devices, Reporting and record keeping requirements.

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

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for part 803 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).

2. Section 803.1 is amended by revising paragraph (a) to read as follows:

§ 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, medical device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and manufacturers must also report certain device malfunctions. Additionally, user facilities and manufacturers must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

* * * * *

3. Section 803.57 is revised to read as follows:

§ 803.57 Annual certification.

(a) All manufacturers required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under § 803.14. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. Foreign manufacturers shall submit their certification by the date on which they would be required to register under § 807.21 of this chapter if they were domestic manufacturers. The certification period will be the 12-month period ending 1 month before the certification date.

(b) The manufacturer shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's medical device reporting system. A manufacturer may determine, based upon its organizational structure, that one individual cannot oversee or have

complete knowledge of the operation of the reporting system at all organizational components or manufacturing sites owned by the firm. In this circumstance, the firm may designate more than one certifying official, each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s).

(c) The report shall contain the following information:

(1) Name, address, telephone number, and FDA registration number or FDA-assigned identification number of the reporting site and whether the firm is a manufacturer;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number of each manufacturing site covered by the certification and the number of reports submitted for devices manufactured at each site;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 803;

(ii) The firm has established a system to implement medical device reporting; and

(iii) Following the procedures of its medical device reporting system, the reporting site submitted the specified number of reports, or no reports, during the 12-month certification period.

(d) The name of the manufacturer and the registration number submitted under paragraph (c)(1) of this section shall be the same as the reporting site that submitted the reports required by §§ 803.52, 803.53 and 803.55. Multi-reporting site manufacturers who choose to certify centrally must identify the reporting sites, by registration number or FDA-assigned identification number and name covered by the certification, and provide the information required by paragraph (c)(2) and (c)(3) of this section for each reporting site.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

4. The authority citation for 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).

5. Part 804 is amended by adding new § 804.30 to read as follows:

§ 804.30 Annual certification.

(a) Distributors required to report under this section shall submit an annual certification report to FDA on form FDA 3381, or electronic equivalent as approved under § 803.14 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration as designated in § 807.21 of this chapter. This certification period will be the 12-month period ending 1 month before the certification date.

(b) The distributor shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's medical device reporting system. A distributor may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or distribution sites owned by the firm. In this circumstance, the firm may designate more than one certifying official (one for each component or site), each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s).

(c) The report shall contain the following information:

(1) Name, address, telephone number, and FDA registration number or FDA assigned identification number of the firm;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number of the distributor covered by the certification and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that;

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement medical device reporting; and,

(iii) Following the procedures of its medical device reporting system, the firm submitted the specified number of reports, or no reports, during the 12-month certification period.

Dated: July 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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