PART 452—MACROLIDE ANTIBIOTIC DRUGS

15. Part 452 is removed.

PART 453—LINCOMYCIN ANTIBIOTIC DRUGS

16. Part 453 is removed.

PART 455—CERTAIN OTHER ANTIBIOTIC DRUGS

17. Part 455 is removed.

PART 460—ANTIBIOTIC DRUGS INTENDED FOR USE IN LABORATORY DIAGNOSIS OF DISEASE

18. Part 460 is removed.

Dated: May 1, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12543 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803 and 804

[Docket No. 98N–0170]

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing reporting by manufacturers, importers, distributors, and health care (user) facilities of adverse events related to medical devices. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA is publishing these amendments in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and withdraws this direct final rule.

DATES: This rule is effective September 24, 1998. Submit written comments on or before July 27, 1998. Submit written comments on the information collection requirements on or before July 13, 1998.

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

FOR FURTHER INFORMATION CONTACT: Patricia A. Spitzig, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2812.

SUPPLEMENTARY INFORMATION:

I. Background

Under the act and the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), FDA issued medical device reporting regulations for manufacturers on September 14, 1984 (49 FR 36326). To correct weaknesses noted in the 1976 amendments, and to better protect the public health by increasing reports of device-related adverse events, Congress enacted the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) that required medical device user facilities and distributors to report certain device-related adverse events.

Distributor reporting requirements became effective on May 28, 1992, following the November 26, 1991 (56 FR 60024), publication of those provisions in a tentative final rule. In the **Federal Register** of September 1, 1993 (58 FR 46514), FDA published a notice announcing that the proposed distributor reporting regulations had become final by operation of law and were now codified in part 804 (21 CFR part 804).

On June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (the 1992 amendments) (Pub. L. 102–112) amending certain provisions of section 519 of the act (21 U.S.C. 360i) relating to reporting of adverse device events. Prior to the 1992 amendments, distributors and manufacturers reported adverse events by using a ''reasonable probability'' standard. Importers may be manufacturers or distributors, depending on their activities. Among other things, the 1992 amendments amended section 519 of the act to change the reporting standard for manufacturers and importers; however, the reporting standard for distributors who are not importers remained the same.

On November 21, 1997, the President signed FDAMA into law. FDAMA made several changes regarding the reporting of adverse events related to devices, including the elimination of reporting requirements for certain distributors, which became effective on February 19, 1998, that are reflected in this direct final rule. However, section 422 of FDAMA states that FDA's regulatory authority under the act, relating to tobacco products, tobacco ingredients, and tobacco additives shall be exercised under the act as in effect on the day before the date of enactment of FDAMA. Because the authority relating to tobacco products remains the same, the reporting requirements for manufacturers and distributors (including distributors who are importers) of cigarettes or smokeless tobacco remain unchanged.

Under part 897, the regulations pertaining to tobacco products, and parts 803 (21 CFR part 803) and 804, the regulations pertaining to device adverse event reporting, importers may be either manufacturers or distributors, depending on their activities. Under parts 897, 803, and 804, importers who repackage or relabel are manufacturers. Similarly, under those sections, importers whose sole activity is distribution of devices are defined as distributors.

As previously stated, the 1992 amendments created a bifurcated reporting standard for distributors, depending on whether they are domestic distributors or importers. When the agency asserted jurisdiction over tobacco products and issued regulations under part 897, tobacco distributors also became subject to this bifurcated reporting standard. Accordingly, the reporting standard applicable to tobacco products distributors has depended on whether the distributor is domestic or an importer. Consistent with section 422 of FDAMA, the direct final rule states that tobacco distributors will continue to use the appropriate reporting standard as described in § 804.25.

Changes made by FDAMA relating to reporting requirements for all medical devices other than tobacco products are as follows:

1. Section 213(a) of FDAMA revised section 519(a) of the act to eliminate distributors as an entity required to report adverse device events. Importers are still required to report under section 519(a) of the act.

2. Section 213(a) also amended section 519(a) of the act to clarify that existing requirements continue to apply for distributors to keep records concerning adverse device events and make them available to FDA upon request.

3. Section 213(a)(2) revoked section 519(d) of the act, which required manufacturers, importers, and distributors to submit to FDA an annual certification concerning the number of

reports filed under section 519(a) in the preceding year. As a result, certification requirements are eliminated.

4. Section 213(c)(1)(A) of FDAMA revised section 519(b)(1)(C) of the act to require that device user facilities submit an annual rather than a semiannual summary of their reports to FDA.

5. Section 213(c)(1)(B) of FDAMA eliminated section 519(b)(2)(C) of the act. This section had required FDA to disclose, upon request, the identity of a device user facility making a report under section 519(b) of the act if the identity of the device user facility was included in a report required to be submitted by a manufacturer, distributor, or importer. As a result of this change by FDAMA, FDA may now disclose the identity of a device user facility only in connection with an action concerning a failure to report or false or fraudulent reporting, a communication to the manufacturer of the device, or to the employees of the Department of Health and Human Services, the Department of Justice, and duly authorized committees and subcommittees of Congress.

II. Final Rule

A. General Approach

1. To implement these provisions, FDA is amending part 804, Distributor Reporting, to reflect that the distributor reporting requirements under that part remain in effect only for distributors (including distributors who are importers) of cigarettes or smokeless tobacco, as defined in part 897. FDA is revoking the reporting requirements under parts 803 and 804 as they apply to distributors who are not importers of all medical devices other than cigarettes or smokeless tobacco. FDA is transferring the reporting requirements for importers of all devices other than cigarettes or smokeless tobacco from part 804 to part 803, Medical Device Reporting. Importers of medical devices will continue to be subject to the same reporting and recordkeeping requirements as they have been under parts 803 and 804, with the exception that, in accordance with FDAMA, importers of devices other than cigarettes or smokeless tobacco products are no longer required to submit annual certifications. They will continue to submit reports on Form 3500A. FDA will review and revise this form as necessary in the near future.

2. Distributor recordkeeping requirements, which also remain in effect, are being transferred from part 804 to part 803, except for those requirements that apply to distributors of cigarettes or smokeless tobacco. The recordkeeping requirements for distributors of cigarettes or smokeless tobacco remain in part 804. No additional requirements for distributor recordkeeping are being added by these changes.

3. In accordance with FDAMA, FDA is also amending part 803 to reflect the change from semiannual to annual reporting for device user facilities, to eliminate certification requirements for manufacturers of medical devices other than cigarettes or smokeless tobacco, and to limit the disclosability of device user facility identities.

4. FDA is not changing or adding any requirements with respect to manufacturers or distributors of cigarettes or smokeless tobacco, as defined in part 897.

B. Specific Changes to Parts 803 and 804

Reporting and recordkeeping requirements for distributors (including distributors who are importers) of cigarettes or smokeless tobacco, as defined in part 897, remain in part 804. Reporting and recordkeeping requirements for manufacturers of all medical devices, including manufacturers of cigarettes or smokeless tobacco, and importers of devices other than cigarettes or smokeless tobacco are contained in part 803. Recordkeeping requirements for distributors of products other than cigarettes or smokeless tobacco are also contained in part 803. These parts are amended as follows:

Changes to Part 803

1. Section 803.1 is amended to reflect that the scope of the regulation now includes reporting requirements for importers, as well as manufacturers and device user facilities, and to clarify that distributors continue to be responsible for maintaining incident files.

2. Section 803.3 is amended to reflect that importers continue to be responsible for reporting, by modifying definitions related to reporting so that importers are included.

3. Section 803.9 is amended by removing paragraph (c)(3), which had required FDA to disclose the name of a device user facility making a report if the adverse event was required to be reported by a manufacturer or distributor. The removal of this paragraph corresponds to the elimination by FDAMA of section 519(b)(2)(C) of the act.

4. Section 803.10 is amended to reflect that importers of medical devices remain responsible for reporting adverse device events, by transferring to this section the requirements that were previously codified under part 804. Furthermore, § 803.10(a)(2) is amended to reflect that device user facilities are now responsible for submitting annual, not semiannual reports. Section 803.10(c)(5) is amended to correspond with the revocation of section 519(d) of the act, which had required annual certification of the number of medical devices report (MDR) reports filed during the preceding year. Revised § 803.10(c)(5) reflects that manufacturers of cigarettes or smokeless tobacco continue to be responsible for complying with the annual certification requirements described in § 803.57.

5. Sections 803.11, 803.17, 803.19, 803.20, 803.22, and 803.56 are amended to reflect that importers continue to be subject to the MDR reporting requirements. Section 803.18 is amended to add ''importers'' to reflect that importers continue to be responsible for maintaining MDR event files, and to clarify that distributors of medical devices also continue to be responsible for establishing device complaint files and maintaining device incident records.

6. Section 803.12 is amended to reflect the change from ''semiannual'' to ''annual'' reports, and the continued inclusion of importers as reporting entities. Section 803.33 is amended to reflect that device user facilities are required to submit annual, not semiannual reports.

7. A new subpart D, consisting of §§ 803.40 and 803.43, has been added to reflect that importers of medical devices continue to be subject to the MDR reporting requirements. These sections represent the transfer of relevant provisions of part 804 (which now applies only to distributors, including those who are importers, of cigarettes or smokeless tobacco) into part 803. Importer reporting and recordkeeping requirements are not being changed by this transfer.

8. Section 803.57 is amended to clarify that the section applies only to manufacturers of cigarettes or smokeless tobacco. This amendment reflects the revocation of section 519(d) of the act, which had required annual certification of the number of MDR reports filed during the preceding year, as it applied to manufacturers of all devices other than cigarettes or smokeless tobacco. This change also reflects the rule of construction in section 422 of FDAMA under which FDA's regulatory authority under the act relating to tobacco products shall be exercised under the act as in effect on the day before the date of enactment of FDAMA.

Changes to Part 804

1. Section 804.1, the scope of part 804, Medical Device Distributor Reporting, is amended to reflect that this part now applies only to distributor reports of adverse events relating to contamination of cigarettes or smokeless tobacco products.

2. Section 804.3 is amended to limit the definition of distributors, for the purposes of part 804, to distributors (including distributors who are importers) of cigarettes or smokeless tobacco products, and to clarify that adverse events that are reportable by distributors are only those related to contamination of cigarettes or smokeless tobacco.

3. Section 804.25 is amended to clarify that adverse events that are reportable under this part are only those related to contamination of cigarettes or smokeless tobacco.

III. Rulemaking Action

In the **Federal Register** of November 21, 1997, FDA described its procedures on when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend existing parts 803 and 804. The companion proposed rule and the direct final rule are substantively identical. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of a significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments to the companion proposed rule will be considered as comments regarding the direct final rule.

FDA has provided a comment period on the direct final rule of July 27, 1998. If the agency receives a significant adverse comment, FDA intends to withdraw this final rule by publication in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the proposed rule in developing a final rule in accordance with usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation notice within 30 days after the comment period ends confirming that the direct final rule will go into effect on September 24, 1998.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

FDA has examined the impact of this direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). 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 this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this direct final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule codifies the elimination of reporting by distributors, other than distributors (including distributors who are importers) of cigarettes or smokeless tobacco, continues reporting by importers (including distributors who are importers), increases protection from disclosure of the identity of device user facilities that have submitted reports, reduces summary reporting by device user facilities from semiannual to annual, eliminates annual certification for manufacturers and distributors (including importers) of medical devices other than cigarettes or smokeless tobacco, and makes other nonsubstantive changes. The agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This direct final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

VI. Paperwork Reduction Act of 1995

This direct final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown as follows with an estimate of the annual reporting and recordkeeping 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 each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Reporting and recordkeeping requirements for manufacturers, importers, user facilities, and distributors of medical devices under FDAMA.

Description: FDAMA contained provisions that affect medical device reporting in a variety of ways. Section 213 of FDAMA eliminated the reporting requirements for medical device distributors (but not for importers), as well as the certification requirements for medical device manufacturers and distributors. This section of FDAMA also modified the summary reporting requirements for user facilities to require annual, rather than semiannual, reporting, and increased confidentiality of user facility identities. However, section 422 of FDAMA states that FDA's regulatory authority under the act relating to tobacco products, tobacco ingredients, and tobacco additives shall be exercised under the act as in effect on the day before the date of enactment of FDAMA. Under this rule of construction, the reporting and certification requirements for manufacturers and distributors (including distributors who are importers) of cigarettes or smokeless tobacco remain unchanged.

This rule amends FDA's regulations in parts 803 and 804 to reflect the changes to medical device reporting made by FDAMA.

This direct final rule eliminates reporting by distributors other than distributors of cigarettes or smokeless tobacco, continues reporting by importers, increases the protection from disclosure of the identity of device user facilities that have submitted reports, reduces summary reporting by device user facilities from semiannual to annual, eliminates annual certification for manufacturers and distributors (including importers) of medical devices other than cigarettes or smokeless tobacco, and makes other nonsubstantive changes.

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
803.19	150	1	150	3	450
803.33	1,800	1	1,800	1	1,800
803.40	195	1	195	3	585
803.56	750	20	15,000	1	15,000
803.57	31	1	31	1	31
804.25	10	1	10	1.5	15
804.30	1,365	1	1,365	1	1,365
804.32	5	1	5	1	5
804.33	0	0	0	1	0
TOTAL	.....	.....	.....	.....	19,251

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
803.17	2,000	1	2,000	2	4,000
803.18	39,764	1	39,764	1.5	59,646
804.34	1,365	1	1,365	2	1,365
804.35	1,365	1	1,365	1.5	2,047
TOTAL	.....	.....	.....	.....	67,058

There are no capital costs or operating and maintenance costs associated with this collection of information.

The burdens under this direct final rule are explained as follows:

Reporting Requirements

Prior to the program change reflected in this rule, § 803.19 allowed manufacturers or user facilities to request an exemption or variance from the reporting requirements. The agency had estimated that it would receive approximately 100 such requests annually. Distributors (including importers) were able to request an exemption or variance from the reporting requirements under § 804.33. Under this rule, § 803.19 is modified to transfer the exemption provisions for importers of medical devices other than cigarettes or smokeless tobacco from § 804.33 to § 803.19. Furthermore, distributors (who are not importers) of medical devices other than cigarettes or smokeless tobacco are no longer required to submit MDR reports under this rule. The estimated burden for § 803.19 is further adjusted to reflect the agency's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.33 required medical device user facilities to submit summary reports semiannually. Under this rule, user facilities are required to submit summary reports annually, thereby significantly decreasing the reporting burden on user facilities. The estimated burden for this section is also adjusted to reflect the agency's actual experience with this type of submission.

Under this rule the reporting requirement for importers of medical devices other than cigarettes or smokeless tobacco previously codified under § 804.25 is being transferred to § 803.40. The estimated burden for importer reporting is based upon the agency's actual experience with this type of submission. The reporting requirements for distributors (including distributors who are importers) of cigarettes or smokeless tobacco have been retained in part 804.

Prior to the program change reflected in this rule, § 803.56 required

manufacturers to submit supplemental reports containing information not known or not available at the time the initial report was submitted. The agency had estimated that it would receive approximately 500 such requests annually. Distributors (including importers) were required to submit supplemental information under § 804.32. Under this rule, § 803.56 is modified to transfer the supplemental reporting requirements for importers of medical devices other than cigarettes or smokeless tobacco from § 804.32. Furthermore, distributors (who are not importers) of medical devices other than cigarettes or smokeless tobacco are no longer required to submit MDR reports (and thus supplemental reports as well) under this rule. The estimated burden for § 803.56 is further adjusted to reflect the agency's actual experience with this type of submission. The agency also notes that any additional information requested by the agency in accordance with § 803.15 is considered to be supplemental information for the purpose of this information collection and is included in the burden estimate for § 803.56.

Prior to the program change reflected in this rule, § 803.57 required medical device manufacturers to annually certify as to the number of reports submitted during the previous year, or that no such reports had been submitted. Distributors (including importers) were required to certify under § 804.30. Under this rule, § 803.57 is modified to require annual certification only for manufacturers of cigarettes or smokeless tobacco. The certification requirements for distributors (including distributors who are importers) of cigarettes or smokeless tobacco have been retained in § 804.30.

Prior to the program change reflected in this rule, § 804.25 required medical device distributors (including importers) to report adverse device events. Under this rule, distributors of medical devices other than cigarettes or smokeless tobacco are no longer required to submit MDR reports, and the reporting requirements for importers of medical devices other than cigarettes or smokeless tobacco have been transferred to part 803. Section 804.25 now requires distributors (including distributors who are importers) of cigarettes or smokeless tobacco to submit MDR reports for adverse events related to contamination of their products. The agency believes that there will be a very small number of MDR reports related to contamination of cigarettes or smokeless tobacco submitted in any given year.

Prior to the program change reflected in this rule, § 804.30 required medical device distributors (including importers) to certify as to the number of MDR reports submitted during the previous year, or that no such reports were submitted. Under this rule, the certification requirement has been removed for distributors (including importers) of medical devices other than cigarettes or smokeless tobacco. Section 804.30 now requires distributors (including distributors who are importers) of cigarettes or smokeless tobacco to submit certifications of the number of MDR reports submitted for adverse events related to contamination of their products. The agency has identified 1,365 distributors of cigarettes or smokeless tobacco, each of which shall submit one certification annually.

Prior to the program change reflected in this rule, § 804.32 required medical device distributors (including importers) to submit supplemental information related to a previously submitted MDR report. Under this rule, distributors of medical devices other than cigarettes or smokeless tobacco are no longer required to submit any MDR reports, and the reporting requirements for importers of medical devices other than cigarettes or smokeless tobacco have been transferred to part 803. Section 804.32 now requires distributors (including distributors who are importers) of cigarettes or smokeless tobacco to submit supplemental information related to a previously submitted MDR report. Because the agency believes that there will be a very small number of MDR reports submitted in any given year, even fewer supplemental submissions are anticipated. The agency also notes that any additional information requested by the agency in accordance with § 804.31 is considered to be supplemental information for the purpose of this information collection and is included in the burden estimate for § 804.32.

Prior to the program change reflected in this rule, § 804.33 allowed medical device distributors (including importers) to request an exemption or variance from the reporting requirements. Under this rule, the exemption provisions for importers of medical devices other than cigarettes or smokeless tobacco are transferred to § 803.19, and distributors (who are not importers) of medical devices other than cigarettes or smokeless tobacco are no longer required to submit any MDR reports under this rule. Section 804.33 now allows distributors (including distributors who are importers) of cigarettes or smokeless tobacco to request an exemption or variance from the reporting requirements. However, because distributors (including distributors who are importers) of cigarettes or smokeless tobacco are required only to submit reports of adverse events related to contamination of their products, the agency does not anticipate any requests for exemptions or variances from the reporting requirements.

Recordkeeping Requirements

Prior to the program change reflected in this rule, § 803.17 required manufacturers and user facilities to establish written procedures for employee education, complaint processing, and documentation of information related to MDR's. Under this rule, the requirements for establishing written MDR procedures for importers of medical devices other than cigarettes or smokeless tobacco have been transferred to § 803.17, and the requirements for distributors (including importers) of cigarettes or smokeless tobacco are retained in § 804.34. The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information related to MDR reporting as part of their internal quality control system. The agency has estimated that no more than 2,000 such entities would be required to establish new procedures, or revise existing procedures, in order to comply with this provision. For those entities, a one-time burden of 10 hours, annualized over a period of 5 years, is estimated for establishing written MDR procedures. The remainder of manufacturers, user facilities, and importers not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Prior to the program change reflected in this rule, § 803.18 required manufacturers and user facilities to establish and maintain MDR event files. Distributors (including importers) were required to establish and maintain MDR event files under § 804.35. Under this rule, § 803.18 is modified to transfer the recordkeeping requirements for importers and other distributors of medical devices other than cigarettes or smokeless tobacco from § 804.35. Recordkeeping requirements for distributors (including distributors who are importers) of cigarettes or smokeless tobacco have been retained in § 804.35.

Prior to the program change reflected in this rule, § 804.34 required distributors (including importers) of all medical devices to establish written

procedures for employee education, complaint processing, and documentation of information related to MDR reports. Under this rule, distributors of medical devices other than cigarettes or smokeless tobacco are no longer required to submit MDR reports. Accordingly, they are no longer subject to the requirement to establish and maintain written MDR procedures although distributors are required to establish device complaint files in accordance with 21 CFR 820.198. Under this rule, the requirement for establishing written MDR procedures for importers of medical devices other than cigarettes or smokeless tobacco is transferred to § 803.17, and the requirements for distributors (including distributors who are importers) of cigarettes or smokeless tobacco are retained in § 804.34. The agency has estimated a one-time burden of 10 hours, annualized over a period of 5 years, for distributors (including distributors who are importers) of cigarettes or smokeless tobacco to establish written MDR procedures under § 804.34.

Prior to the program change reflected in this rule, § 804.35 required distributors (including importers) to establish and maintain MDR event files. Under this rule, the recordkeeping burdens for distributors (including importers) of medical devices other than cigarettes or smokeless tobacco have been transferred to § 803.18. Recordkeeping requirements for distributors (including distributors who are importers) of cigarettes or smokeless tobacco are retained in § 804.35.

As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection provisions of this direct final rule by July 13, 1998, to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number.

VII. Request for Comments

Interested persons may, on or before July 27, 1998, submit to the Docket Management Branch (address above) written comments regarding this rule. The comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the companion proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and this direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Parts 803 and 804

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 and 804 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 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, device user facilities, importers, and manufacturers, as defined in § 803.3, must report deaths and serious injuries to which a device has or may have caused or contributed, must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. Medical device distributors, as defined in § 803.3, are also required to maintain incident files. Furthermore, manufacturers and importers are also required to report certain device malfunctions. 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 803.3 is amended by redesignating paragraphs (m) through (ee) as paragraphs (n) through (ff), respectively; by revising the last sentence of the introductory text of paragraph (c), paragraph (c)(1), and redesignated paragraphs (p), (p)(1), and (r)(2); and by adding paragraphs (g) and (m) to read as follows:

§ 803.3 Definitions.

* * * * *

(c) * * * Manufacturers and importers are considered to have become aware of an event when:

(1) Any employee becomes aware of a reportable event that is required to be reported by an importer within 10 days, or by a manufacturer within 30 days or within 5 days under a written request from FDA under § 803.53(b); and

* * * * *

(g) *Distributor* means, for the purposes of this part, any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under § 803.3(o). For the purposes of this part, distributors do not include distributors of cigarettes or smokeless tobacco.

* * * * *

(m) *Importer* means, for the purposes of this part, any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under § 803.3(o). For the purposes of this part, importers do not include importers of cigarettes or smokeless tobacco.

* * * * *

(p) *Manufacturer or importer report number* means the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of three parts as follows:

(1) The FDA registration number for the manufacturing site of the reported device, or for the importer. (If the

manufacturing site or the importer does not have a registration number, FDA will assign a temporary number until the site is officially registered. The manufacturer or importer will be informed of the temporary number.);

* * * * *

(r) * * *

(2) An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury; or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause a death or serious injury if the malfunction were to recur.

* * * * *

§ 803.9 [Amended]

4. Section 803.9 *Public availability of reports* is amended by adding ''or'' after the semicolon at the end of paragraph (c)(2), by removing paragraph (c)(3), and by redesignating paragraph (c)(4) as paragraph (c)(3).

5. Section 803.10 is amended by revising the heading and paragraphs (a)(2) and (c)(5), and by adding paragraph (b) to read as follows:

§ 803.10 General description of reports required from user facilities, importers, and manufacturers.

(a) * * *

(2) User facilities must submit annual reports as described in § 803.33.

(b) Importers must submit MDR reports of individual adverse events within 10 working days after the importer becomes aware of an MDR reportable event as described in § 803.3. Importers must submit reports of device-related deaths or serious injuries to FDA and the manufacturer and reports of malfunctions to the manufacturer.

(c) * * *

(5) For manufacturers of cigarettes or smokeless tobacco, annual certification to FDA of the number of MDR reports filed during the preceding year as described in § 803.57.

§ 803.11 [Amended]

6. Section 803.11 *Obtaining the forms* is amended in the first sentence by adding the word ''\, importers,'' after the phrase ''User facilities''.

7. Section 803.12 is amended by revising paragraph (b) to read as follows:

§ 803.12 Where to submit reports.

* * * * *

(b) Each report and its envelope shall be specifically identified, e.g., ''User Facility Report,'' ''Annual Report,'' ''Importer Report,'' ''Manufacturer Report,'' ''5–Day Report,'' ''Baseline Report,'' etc.

§ 803.17 [Amended]

8. Section 803.17 *Written MDR procedures* is amended in the introductory paragraph by adding the word ''\, importers,'' after the phrase ''User facilities''.

9. Section 803.18 is amended by revising the heading, the first sentence of paragraphs (a) and (b)(1) introductory text, paragraphs (b)(1)(ii) and (b)(2), and the second sentence of paragraph (c), and by adding paragraph (d) to read as follows:

§ 803.18 Files and distributor records.

(a) User facilities, importers, and manufacturers shall establish and maintain MDR event files. * * *

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. * * *

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (e.g., an importer, distributor, or manufacturer).

(2) User facilities, importers, and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) * * * Manufacturers and importers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. * * *

(d)(1) A device distributor shall establish device complaint files in accordance with § 820.198 of this chapter and maintain an incident record containing any information, including any written or oral communication, that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device. Device incident records shall be prominently identified as such and shall be filed by device.

(2) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the design and expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the record.

(3) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

§ 803.19 [Amended]

10. Section 803.19 *Exemptions, variances, and alternative reporting requirements* is amended by adding in paragraphs (b) and (c) the word ''\, importers,'' before the phrase ''or user facility,'' and by adding in paragraph (c) a comma after the word ''variance''.

11. Section 803.20 is amended by revising the last sentence of introductory text of paragraph (a), paragraph (a)(1), and the first sentence of paragraph (a)(2), and by adding paragraph (b)(2) to read as follows:

§ 803.20 How to report.

(a) * * * The form has sections that must be completed by all reporters and other sections that must be completed only by the user facility, importer, or manufacturer.

(1) The front of FDA Form 3500A is to be filled out by all reporters. The front of the form requests information regarding the patient, the event, the device, and the ''initial reporter'' (i.e., the first person or entity that submitted the information to the user facility, manufacturer, or importer).

(2) The back part of the form contains sections to be completed by user facilities, importers, and manufacturers. * * *

(b) * * *

(2) Importers are required to submit MDR reports to FDA and the device manufacturer, except for malfunctions which are reported to the manufacturer only:

(i) Within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

(ii) Within 10 working days of receiving information that a device marketed by the importer has malfunctioned and that such a device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

* * * * *

§ 803.22 [Amended]

12. Section 803.22 *When not to file* is amended by adding in paragraphs (a) and (b)(1) the word ‘‘, importer,’’ after the word ‘‘facility’’.

§ 803.33 [Amended]

13. Section 803.33 *Semiannual reports* is amended by revising the heading to read ‘‘Annual reports’’; in introductory text of paragraph (a) by removing the phrase ‘‘(for reports made July through December) and by July 1 (for reports made January through June)’’; in introductory text of paragraph (a) and paragraphs (a)(5), (a)(7) introductory text, and (c) by removing the word ‘‘semiannual’’ wherever it appears and adding in its place the word ‘‘annual’’; in paragraph (a)(2) by removing the phrase ‘‘and period, e.g., January through June or July through December’’; and by adding in paragraph (a)(7)(vi) the word ‘‘importer,’’ after the word ‘‘distributor,’’.

14. Subpart D, consisting of §§ 803.40 and 803.43, is added to read as follows:

Subpart D—Importer Reporting Requirements

Sec.

803.40 Individual adverse event reporting requirements; importers.

803.43 Individual adverse event report data elements.

Subpart D—Importer Reporting Requirements

§ 803.40 Individual adverse event reporting requirements; importers.

(a) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 803.43 on FDA form 3500A as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b) An importer shall submit to the manufacturer a report containing information required by § 803.43 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the importer’s own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

§ 803.43 Individual adverse event report data elements.

(a) Each importer that submits a report on an MDR reportable event shall complete and submit the applicable portions of FDA form 3500A in so far as the information is known or should be known to the importer, and submit it to FDA, and to the manufacturer as required by § 803.40.

(b) Each importer shall submit the information requested on FDA form 3500A, including:

(1) Identification of the source of the report.

(i) Type of source that reported the event to the importer (e.g., lay user owner, lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Importer report number;

(iii) Name, address, and telephone number of the source that reported the event to the importer (e.g., distributor, user facility, practitioner, etc.); and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the importer became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event (e.g., death, serious illness, serious injury, or malfunction), and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event, including:

(i) Who was operating or using the device when the event occurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of the evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

§ 803.56 [Amended]

15. Section 803.56 *Supplemental reports* is amended in the introductory paragraph and in paragraphs (a) and (b) by adding the words ‘‘or importer’’ after the word ‘‘manufacturer’’.

§ 803.57 [Amended]

16 Section 803.57 *Annual certification* is amended in paragraphs (a) and (d) by removing the word ‘‘manufacturers’’ wherever it appears and by adding in its place the phrase ‘‘manufacturers of cigarettes or smokeless tobacco’’, and in paragraphs (b), (c)(1), and (d) by removing the word ‘‘manufacturer’’ wherever it appears and adding in its place the phrase ‘‘manufacturer of cigarettes or smokeless tobacco’’.

PART 804—MEDICAL DEVICE REPORTING FOR DISTRIBUTORS OF CIGARETTES OR SMOKELESS TOBACCO

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

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

18. Part 804 is amended by revising the heading to read as set forth above.

19. Section 804.1 is amended by revising paragraph (a) to read as follows:

§ 804.1 Scope.

(a) FDA is requiring distributors of cigarettes or smokeless tobacco to report deaths, serious illnesses, and serious injuries that are attributed to contamination of a cigarette or smokeless tobacco product. Distributors of cigarettes or smokeless tobacco are also required to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that these products are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, distributors of cigarettes or smokeless tobacco are required to establish and maintain complaint files or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

* * * * *

20. Section 804.3 is amended by revising paragraph (d), and in paragraphs (m)(1) and (m)(2) by adding the phrase ''related to the contamination of cigarettes or smokeless tobacco'' after the word ''event'' to read as follows:

§ 804.3 Definitions.

* * * * *

(d) *Distributor* means, for the purpose of this part, any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption, but who does not repackage or otherwise change the container, wrapper, or labeling of the product package. Common carriers are not considered distributors for the purposes of this part.

* * * * *

§ 804.25 [Amended]

21. Section 804.25 *Reports by distributors* is amended in paragraph (a)(1) by removing the words ''a device'' and adding in their place the phrase ''contamination of a cigarette or smokeless tobacco product''; in paragraph (a)(2) by removing the phrase ''one of its marketed devices'' and adding in its place the phrase ''contamination of one of its cigarette or smokeless tobacco products''; and by removing paragraph (c).

Dated: May 1, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12614 Filed 5–11–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1240

[Docket No. 97P–0418]

Revocation of Lather Brushes Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulation pertaining to the treatment, sterilization, handling, storage, marking, and inspection of lather brushes. FDA is revoking this regulation because the regulation is no longer necessary to protect the public health.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Policy Development and Coordination Staff (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

DATES: This final rule is effective June 11, 1998.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 1997 (62 FR 54398), FDA proposed to revoke a regulation pertaining to the treatment, sterilization, handling, storage, marking, and inspection of lather brushes. The preamble to the proposal explained that the lather brush regulation was originally published in 1949 by the Federal Security Agency and was intended to prevent cases of cutaneous anthrax through lather brushes made from animal hair or bristles. A Government reorganization transferred the Federal Security Agency's functions to the then-Department of Health, Education, and Welfare (now known as the Department of Health and Human Services), and responsibility for the rule was later assigned, in 1975, to FDA. The rule was codified at § 1240.70 (21 CFR 1240.70).

FDA proposed to revoke the regulation because it was unaware of any reliance on the lather brush requirements or of any current concerns associated with lather brushes and because the regulation was no longer necessary to protect the public health. The proposal also noted that the then-Center for Disease Control (now the Centers for Disease Control and Prevention) revoked a similar lather brush regulation in 1985 on the grounds that no case of cutaneous anthrax in the United States had been associated with lather brushes since 1930.

FDA received no comments on the proposal. Consequently, this final rule revokes § 1240.70.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule eliminates certain manufacturing requirements for lather brushes, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.