

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DDM

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA-2008-N-0310]

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Certifier Seese

Medical Devices; Medical Device Reporting; Baseline Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device reporting regulations to remove a requirement for baseline reports that the agency deems no longer necessary. Currently, manufacturers provide baseline reports to FDA that include the FDA product code and the premarket approval or premarket notification number. Because most of the information in these baseline reports is also submitted to FDA in individual adverse event reports, FDA is removing the requirement for baseline reports. The removal of this requirement will eliminate unnecessary duplication and reduce the manufacturer's reporting burden. FDA is amending the regulation in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, we are 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 we receive a significant adverse comment and withdraw this direct final rule.

DATES: This rule is effective [insert date 135 days after date of publication in the **Federal Register**]. Submit written or electronic comments by [insert date 75 days after date of publication in the **Federal Register**]. If we receive no

significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0310, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:
Division of Dockets Management (HFA–305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information

provided. For additional information on submitting comments, see section IX of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Howard A. Press, Center for Devices and Radiological Health (HFZ-530), Food and Drug Administration, 1350 Piccard Dr, Rockville, MD 20850, 240-276-3457.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of the Rule?

In the **Federal Register** of December 11, 1995 (60 FR 63578), FDA published a final rule revising part 803 (21 CFR part 803) and requiring medical device manufacturers to submit certain reports relating to adverse events, including a requirement under § 803.55 to submit baseline reports on FDA Form 3417 or an electronic equivalent. Section 803.55 requires manufacturers to submit baseline reports when the manufacturer submits the first adverse event report under § 803.50 for a device model. In addition, § 803.55 requires annual updates of each baseline report.

The baseline report includes address information for the reporting and manufacturing site for the device, device identifiers, the basis for marketing for the device (e.g., the 510(k) number or PMA number), the FDA product code, the shelf life of the device (if applicable) and the expected life of the device, the number of devices distributed each year, and the method used to calculate that number. In the **Federal Register** of July 31, 1996 (61 FR 39868), FDA

stayed the requirement for manufacturers to submit information on the number of devices distributed each year and the method used to calculate that number, because of questions raised about the feasibility of obtaining such information and the usefulness of such information once submitted to FDA.

With the requirement for these two data elements stayed, the data submitted in baseline reports largely overlapped with the data submitted in individual adverse event reports. That is, FDA had access to much of the information included in baseline reports through the individual adverse event reports submitted on the MedWatch mandatory reporting form (FDA Form 3500A). Two notable exceptions were the basis for marketing and the FDA product code, data elements that were included in the baseline reports but were not included in the FDA Form 3500A and its instructions.

The basis for marketing and the FDA product code were, however, subsequently incorporated into the FDA Form 3500A and its instructions. In the **Federal Register** of December 27, 2004 (69 FR 77256), FDA announced proposed modifications to FDA Form 3500A, which included adding an entry for the basis for marketing (PMA or 510(k) number). In the **Federal Register** of December 7, 2005 (70 FR 72843), FDA announced that the Office of Management and Budget approved these modifications under the Paperwork Reduction Act of 1995. FDA also modified the instructions for FDA Form 3500A to state that manufacturers use the FDA product code when completing the entry for “Common Device Name” on FDA Form 3500A.

With the addition of these two data elements (basis for marketing and FDA product code) to FDA Form 3500A and its instructions, the information submitted in FDA Form 3500A largely replicates the information submitted in baseline reports. As a result, the agency deems the baseline reporting

requirement in § 803.55 no longer necessary. The agency believes that removing § 803.55 will reduce the reporting burden for manufacturers without impairing the agency's receipt of device adverse event information.

II. What Does This Direct Final Rulemaking Do?

In this direct final rule, FDA is removing § 803.55, which requires manufacturers to submit a baseline report when they submit the first report under § 803.50 involving a device model and provide annual updates thereafter. In addition, this direct final rule makes conforming amendments to §§ 803.1(a), 803.10(c), and 803.58(b) to remove references to baseline reports and to § 803.55. Finally, this direct final rule removes the terms "device family" and "shelf life" from the definitions in § 803.3 because these terms are used only in the context of baseline reports.

III. What Are the Procedures for Issuing a Direct Final Rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures" that described when and how FDA will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial changes to existing regulations. We anticipate no significant adverse comment.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule that is identical to the direct final rule. 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 any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any

comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comment, we intend to withdraw this final rule before its effective date by publication of a notice 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 an adverse comment is significant and warrants withdrawing a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). 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 will not be considered a significant adverse comment, unless the comment states 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, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq.*). If we receive no significant adverse comment during the specified

comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

IV. What is the Legal Authority for This Rule?

FDA is issuing this direct final rule under the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 360i, 371, and 374).

V. What is the Environmental Impact of This Rule?

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

VI. What is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 not a significant regulatory action as defined by 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 direct final rule amends the existing medical device reporting regulation to remove § 803.55, which requires that manufacturers submit baseline reports, and makes conforming amendments to §§ 803.1(a), 803.3, 803.10(c), and 803.58(b) to remove references to baseline reports and to § 803.55 and to

remove the terms “device family” and “shelf life.” This final rule does not impose any new requirements but instead removes a reporting requirement for manufacturers that FDA deems no longer necessary. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. What are the Federalism Impacts of This Rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive

order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 803

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 part 803 is 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.

§ 803.1 [Amended]

■ 2. Section 803.1 is amended in paragraph (a), in the fourth sentence, by removing the phrase “and baseline reports”.

§ 803.3 [Amended]

■ 3. Section 803.3 is amended by removing the definitions for “Device family” and “Shelf life”.

§ 803.10 [Amended]

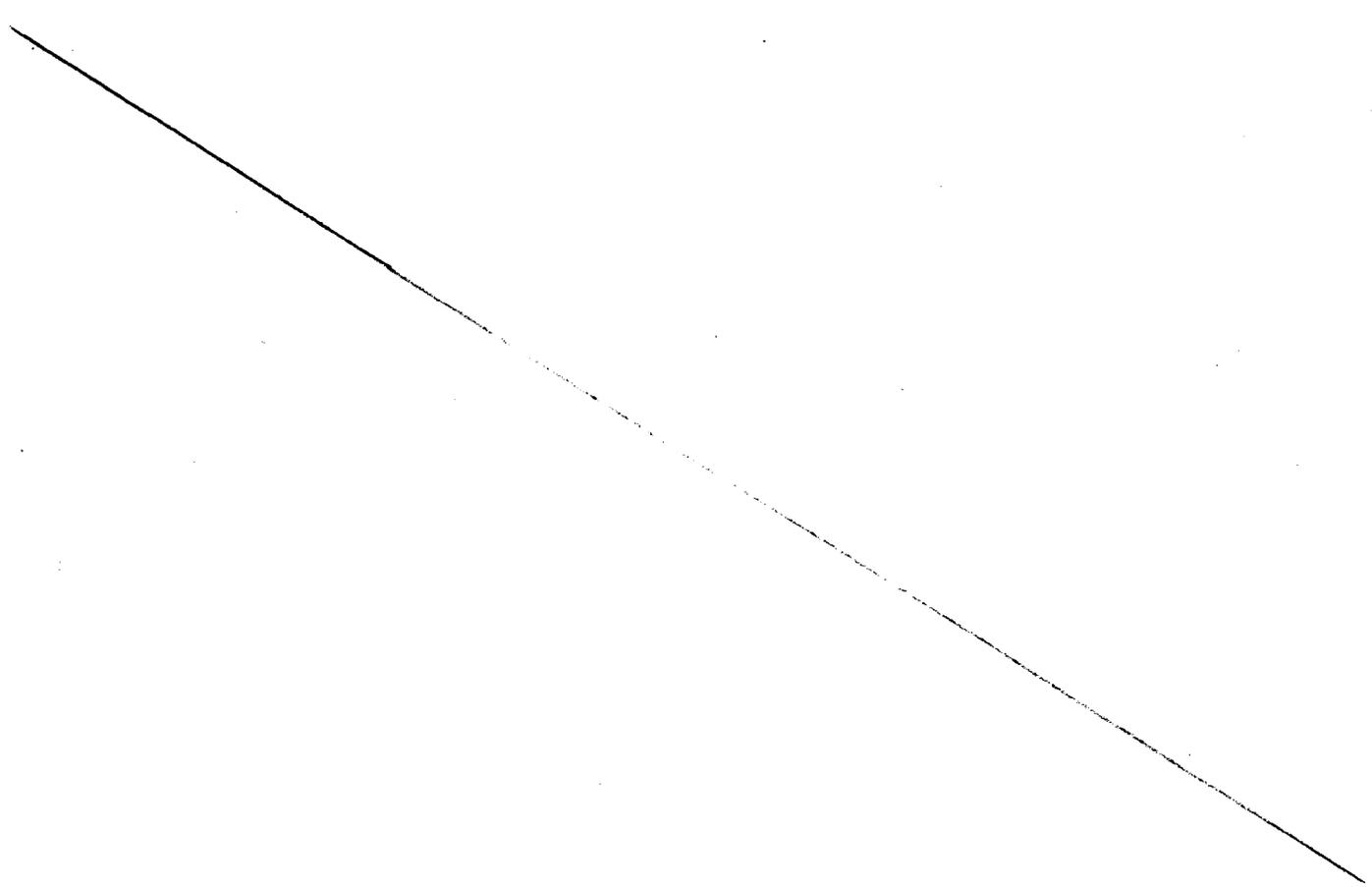
■ 4. Section 803.10 is amended by removing paragraph (c)(3) and redesignating paragraph (c)(4) as paragraph (c)(3).

§ 803.55 [Removed]

■ 5. Section 803.55 is removed.

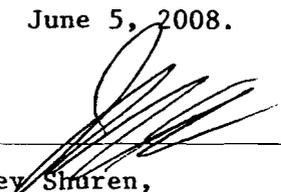
§ 803.58 [Amended]

■ 6. Section 803.58 is amended in paragraph (b)(1) by removing “803.55,”.



Dated: 6/5/08

June 5, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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