(iii) Patient gender; and
(iv) Patient weight.
(2) *Adverse experience.*
(i) Outcome attributed to adverse experience;
(ii) Date of adverse experience;
(iii) Date of report;
(iv) Description of adverse experience;
(v) Description of relevant tests, including dates and laboratory data; and
(vi) Other relevant patient history, including preexisting medical conditions.
(3) *Suspect medical product(s).*
(i) Name;
(ii) Dose, frequency, and route used;
(iii) Therapy dates;
(iv) Diagnosis for use (indication);
(v) State whether adverse experience abated after product use stopped or dose reduced;
(vi) Lot number;
(vii) Expiration date;
(viii) State whether adverse experience reappeared after reintroduction of the product;
(ix) NDC number, or other unique identifier; and
(x) Concomitant medical products and therapy dates.
(4) *Initial reporter information.*
(i) Name, address, and phone number;
(ii) Whether the initial reporter is a health professional;
(iii) Occupation; and
(iv) Whether the initial reporter also sent a copy of the report to FDA.
(5) *Applicant information.*
(i) Applicant name and contact office address;
(ii) Telephone number;
(iii) Report source(s) (e.g., literature, study);
(iv) Date received by applicant;
(v) Application number and type;
(vi) Type of report being submitted (e.g., 15-day, periodic, followup);
(vii) Adverse experience term(s); and
(viii) Manufacturer report number.
(g) *Electronic format for submissions.* (1) Safety report submissions, including ICSRs and any attached documentation and the descriptive information in periodic reports, must be in an electronic format that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

(2) *Waivers.* Persons subject to the requirements of paragraph (c) of this section may request, in writing, a temporary waiver of the requirements in paragraph (g)(1) of this section. These waivers will be granted on a limited basis for good cause shown. If the agency grants the waiver, the person must submit reports required under this section on paper within the required time periods in a form that FDA can process, review, and archive. FDA will issue guidance on how to provide the paper submission. Requests for waivers must be submitted in accordance with § 600.90.

* * * * *

(i) *Patient privacy.* For nonvaccine biological products, an applicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant should assign a unique code to each report. The preferred methodology for determining the identification code will be set forth in guidance. The applicant should include the name of the reporter from whom the information was received, unless the reporter is the patient. The names of patients, health care professionals, hospitals, and geographical identifiers in adverse experience reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter. For vaccine adverse experience reports, these data will become part of the CDC Privacy Act System 09–20–0136, ''Epidemiologic Studies and Surveillance of Disease Problems.'' Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

* * * * *

8. Section § 600.81 is amended:

a. By removing the phrase ''licensed manufacturer'' each time it appears and by adding in its place the word ''applicant'';

b. By designating the existing text as paragraph (a) and by adding a new heading for paragraph (a); and

c. By adding new paragraph (b) to read as follows:

§ 600.81 Distribution reports.

(a) Reporting requirements. * * *

(b)(1) *Electronic format.* Except as provided for in paragraph (b)(2) of this section, the distribution reports required under paragraph (a) of this section must be submitted to the agency in electronic format in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

(2) *Waivers.* An applicant may request, in writing, a temporary waiver of the requirements in paragraph (b)(1) of this section. These waivers will be granted on a limited basis for good cause shown. If the agency grants the waiver, the applicant must submit reports required under this section on paper within the required time period in a form that FDA can process, review, and archive. FDA will issue guidance on how to provide the paper submission. Requests for waivers must be submitted in accordance with § 600.90.

§ 600.90 [Amended]

9. Section 600.90 is amended by removing the phrase ''licensed manufacturer'' each time it appears and by adding in its place the word ''applicant''.

Dated: August 5, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19682 Filed 8–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA–2008–N–0393]

RIN 0910–AF86

Medical Device Reporting: Electronic Submission Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its postmarket medical device reporting regulation to require that manufacturers, importers, and user facilities submit mandatory reports of individual medical device adverse events, also known as medical device reports (MDRs) to the agency in an electronic format that FDA can process, review, and archive. Mandatory electronic reporting would improve the agency's process for collecting and analyzing postmarket medical device adverse event information. The proposed regulatory changes would provide the agency with a more efficient data entry process that would allow for timely access to medical device adverse event information and identification of emerging public health issues. Elsewhere in this issue of the **Federal Register**, FDA is also announcing a draft guidance document that provides recommendations on how to prepare and submit electronic MDRs to FDA in a manner that satisfies the requirements

of this proposed regulation. The proposal also includes modifications to the regulations specifying the content of required MDRs to better track information already solicited on the FDA Form 3500A.

DATES: November 19, 2009. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by September 21, 2009, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0393 and/or RIN number 0910–AF86, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

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(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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 the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section 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(s), 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.

Information Collection Provisions: The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax or e-mail comments regarding the information collection provisions by September 21, 2009, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to 202–395–7285 or e-mailed to *OIRA_submission@omb.eop.gov*. Please reference this proposed rule and OMB Control Number 0910–0437 and mark your comments to the Attention of the FDA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Howard Press, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Building 66, rm. 3320, Silver Spring, MD 20993–0002, 301–796–6087.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In this proposal, we provide background information on the current status of FDA's medical device reporting requirements, explain the revisions we are proposing here, and describe our approach to electronic medical device reporting.

For over 20 years, FDA has received postmarket MDRs in a paper format. This proposed rule to require the electronic submission to FDA of most MDRs is an important step towards improving the agency's systems for collecting and analyzing postmarket MDRs. The proposed rule includes reports of deaths, serious injuries, and malfunctions that must be reported to FDA in initial 5-day, 10-day, or 30-day individual MDRs or in supplemental reports. We believe this proposed rule would have the following benefits:

- Reduce industry's time and costs associated with transcribing data from internal data management systems to paper and mailing the paper reports to the agency,

• Eliminate the agency's transcription errors, time, and costs associated with receiving paper reports and transcribing data to electronic format for review and analysis,

• Expedite the agency's access to safety information in a format that would support more efficient and comprehensive data analysis and reviews, and

• Enhance the agency's ability to rapidly communicate information about suspected problems to the medical device industry, health care providers, consumers, and other government agencies.

In addition, this proposed rule is consistent with the Government Paperwork Elimination Act (Public Law 105–277) requirement that Federal agencies allow individuals or entities to submit information or transact business with the agency electronically.

A. What Are the Medical Device Reporting Requirements?

The requirements of current medical device reporting regulations are summarized in sections I.A.1 to I.A.3 of this document. In addition, we address changes to these regulations to be effected outside of this proposed rule.

Current MDR regulations (part 803 (21 CFR part 803)) require manufacturers and importers of marketed medical devices, and user facilities, to submit postmarket reports of individual medical device adverse events to FDA on the FDA Form 3500A.

1. What Are the Current Reporting Requirements for Manufacturers and What Is Their Status?

The current MDR regulation requires that manufacturers of medical devices submit a postmarket MDR of an individual adverse event no later than 30 calendar days after becoming aware of information that a device the manufacturer markets may have caused or contributed to a death, serious injury, or malfunction (§ 803.50). This report must be submitted on the FDA Form 3500A, (§ 803.20), and contain information described in § 803.52.

In addition, the regulation requires manufacturers to provide supplemental information about such events, on an FDA Form 3500A, within 30 calendar days of obtaining information should such information become available after the initial MDR was filed with FDA (§ 803.56). In instances where the medical device adverse event resulted in remedial action to prevent an unreasonable risk of substantial harm to the public health, or at the discretion of the agency, the regulation requires the manufacturer to submit an MDR to the agency no later than 5 working days after becoming aware of the information (§ 803.53).

Title II, section 227, of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), amended section 519 of the Federal Food, Drug, and Cosmetic Act (the act) to require that FDA establish criteria for manufacturer reports of malfunctions for most class I and certain class II devices that include requiring those reports to be in summary form and made on a quarterly basis. The types of events required to be reported are unchanged. FDA intends to address changes necessitated by this statutory change separately from this proposed rule, and will address requirements for submission of those new summary malfunction reports at that time. However, some individual malfunction reports will continue to be required even after the FDAAA-related changes, and as explained below, the rule proposed here does address submission of individual malfunction reports to the agency.

2. What Are the Current Reporting Requirements for Importers?

The MDR regulation requires that importers of medical devices submit a postmarket MDR to the agency and the manufacturer no later than 30 calendar days after becoming aware of information that reasonably suggests that one of the importer's marketed devices may have caused or contributed to a death or serious injury (§ 803.40(a)). Importers must submit reports to the manufacturer no later than 30 calendar days after becoming aware of information that reasonably suggests that one of the importer's marketed devices has malfunctioned and that this 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 (§ 803.40(b)). These reports must be submitted on the FDA Form 3500A (see § 803.20) and contain the information specified in § 803.42.

3. What Are the Current Reporting Requirements for User Facilities?

The MDR regulation requires that user facilities submit a postmarket MDR of death to the agency and an MDR of death or serious injury to the device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death or a serious injury of a patient of the facility. (§ 803.30(a)). The regulation requires that user facilities submit postmarket reports of serious injury to the agency within 10 working days if the manufacturer of the device is unknown or cannot be identified (§ 803.30(a)(2)). These reports must be submitted on the FDA Form 3500A (see § 803.20(a)), and include the information described in § 803.32.

In addition, user facilities are required to submit to the agency an annual summary of the reports they sent to manufacturers and the FDA, using FDA Form 3419 (§ 803.33). The proposal to require submission of reports to FDA in an electronic format does not apply to user facility annual reports made under § 803.33, although other changes to § 803.33 are proposed as explained in section I.B of this document.

B. What Format Is Currently Used for Submitting Postmarket Medical Device Reports?

Current regulations at § 803.20(a) require that user facilities, importers, and manufacturers use the FDA Form 3500A to submit mandatory reports about FDA-regulated devices. This requirement took effect July 31, 1996 (see 60 FR 63578, December 11, 1995; 61 FR 16043, April 11, 1996).

Certain blocks of the FDA Form 3500A are required only for user facilities, while others are required only for manufacturers (see § 803.20(a)(2)).

Subsequent to its initial adoption, FDA revised the Form 3500A and its instructions, adding elements including the premarket approval application (PMA) or 510(k) number for the device, and two questions regarding reprocessed single-use devices. The agency was required to revise the form to include the questions regarding reprocessed single-use devices under section 303 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250). The revised FDA Form 3500A is approved under the PRA, under OMB control number 0910–0291.

FDA Form 3500A has been routinely completed on paper and transmitted to FDA by mail, requiring FDA to manually input information from those reports into its internal electronic systems before it can be reviewed and analyzed. This process is extremely time consuming, costly, and susceptible to data entry errors. Because FDA regulations at § 803.14 provide for the possibility of voluntary electronic submission of MDRs, with agency permission, several regulations in part 803 refer to submission of reports using the FDA Form 3500A ''or an electronic equivalent approved under section 803.14.'' (See, e.g., §§ 803.30, 803.40, and 803.53.) However, reporters have not made use of section 803.14 to

pursue voluntary electronic submission of MDRs, and FDA's legacy systems were not in general designed to accept submission of MDRs in electronic format.

C. Why Is FDA Proposing to Require Electronic Submission of MDRs?

When a medical device has been cleared for marketing and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits or risks of the product, and evaluation of this information is important for all products to ensure their safe use. Historically, FDA has received almost all postmarket MDRs on paper through the mail. When data elements are provided to FDA on only paper, the information must be entered by hand into an electronic format for review and analysis. This process is extremely time consuming, costly, and susceptible to data entry errors.

The electronic submission of medical device reports would lead to more efficient reviews, enhancing our ability to rapidly disseminate significant information to the medical device industry, health care providers, and consumers, in support of FDA's public health mission.

Electronic submissions would also improve the speed and efficiency of both industry and agency operations. Electronic reporting can benefit industry by reducing the costs associated with collating, copying, storing, retrieving, and mailing paper medical device reports to the agency on FDA Form 3500A. In addition, the agency benefits from the elimination of manual data entry processes and reductions in physical storage for paper copies of the FDA Form 3500A. Based on low rates of participation in prior pilot voluntary electronic MDR submission programs, FDA believes that without a regulation requiring electronic submission of MDRs a large number of medical device firms and user facilities would resist changing their procedures for a long period of time. This delay would hinder our achieving the benefits of standardized formats and quicker access to MDR data.

1. What Are the Options for Electronic Reporting?

FDA's Center for Devices and Radiological Health (CDRH) has established its MDR databases currently to support two options for electronic submission of MDRs: One designed for low volume reporting and one designed for high volume reporting. Both options make use of the FDA Electronic Submission Gateway (FDA ESG), a secure electronic portal described further in this document, for transmission of reports to FDA. In accordance with 21 CFR 11.2(b), CDRH is now accepting on a voluntary basis, in lieu of paper, MDRs prepared and transmitted in accordance with these options. More information on electronic submission of MDRs is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127932.htm*.

For low-volume medical device reporting (few or infrequent MDRs), the current approach developed by the agency uses the CDRH eSubmitter (CeSub) software. The CeSub software allows for the submission of one MDR at a time. The software provides the following tools:

- Save address and contact information,
- Search for a Product Code,
- Search to locate a patient or Device Problem Code,
- Search to find manufacturer evaluation codes (method, result, and conclusion),
- Attach documents when additional information needs to be provided,
- Produce a ''missing data report'' to help ensure that all required information is supplied before submission to FDA.

Once the MDR is completed, the file is ''packaged for submission.'' The package generates an electronic version of the FDA Form 3500A, which can be submitted to FDA using the FDA ESG. The final CeSub-generated report can also be saved or printed, for recordkeeping or to provide reports to manufacturers or other entities outside of FDA. The CeSub software and instructions for installation are free and available at: *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm*. We may sometimes update or change our methodology, approach or software to improve the low-volume reporting experience.

Reporters with large volumes of MDRs may prefer the second option, called the Health Level 7 Individual Case Safety Report (HL7 ICSR). The HL7 ICSR was developed in conjunction with the HL7 standards organization to support the exchange of electronic data. This option allows for the extraction directly from the reporter's database of information to populate an MDR, production of the appropriate data output, and transmission of the MDRs to the FDA ESG. The HL7 ICSR supports the batch submission of more than one individual MDR at a time. Reporters developing applications using the HL7 ICSR standard may also build functions for saving or printing those reports.

The draft guidance document announced elsewhere in this **Federal Register** provides information on both options for electronic submission of MDRs.

2. What Is the FDA Electronic Submission Gateway (ESG)?

The FDA ESG is the entry point for all electronic submissions to the agency. The FDA ESG is available 24 hours a day, 7 days a week. Information on the FDA ESG is available at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*. To use the FDA ESG, reporters need to have a digital certificate. A digital certificate is an attachment to an electronic message that allows the recipient to authenticate the identity of the sender via third party verification from an independent certificate authority. Digital certificates are used to identify encryption and decryption codes between message senders and recipients. Information on digital certificates can be found at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113223.htm*.

3. How Do I Know FDA Received My Electronic Submission and It Was Successfully Processed?

FDA's electronic submission processing system sends the submitter three different acknowledgments (messages) for each submission. Acknowledgment 1 comes from the ESG and indicates your submission was received. Acknowledgment 2 is sent by the ESG and indicates the submission reached CDRH. CDRH sends Acknowledgment 3 and notifies you whether your submission was successfully loaded into CDRH's adverse event database or the submission contained errors (specified in the acknowledgment) during validation and loading. If your submission contained errors, the errors need to be corrected and the corrected reports resent.

II. Description of the Proposed Rule

A. How Would the Rule Address Submission of Reports in Electronic Format?

This rule would revise § 803.12 to require that manufacturers, importers, and user facilities submit postmarket MDRs to the agency in an electronic format that FDA can process, review, and archive. Under the proposal, FDA will periodically issue information on

file formats, preparation and organization of files, media, method of transmission, and other relevant technological specifications for providing reports in an electronic format that FDA can process, review, and archive. Proposed new § 803.23 would direct reporters to the agency's Web site to find the most updated relevant information. Reports between manufacturers, importers, and user facilities would not be subject to the requirement of submission in electronic format, and may be in any format the recipient can read.

The rule would make conforming changes throughout part 803 to reflect the proposed requirement to submit reports to FDA in electronic format. These changes include removing § 803.11, which currently addresses obtaining paper forms, and removing § 803.14, which currently provides for voluntary electronic submission of reports with FDA consent. The proposal would amend § 803.19, which already addresses exemptions or variances from any of the requirements of part 803, to specifically address exemption or variance from the requirement to submit reports to FDA in electronic format. Other changes include removing references to ''electronic equivalent[s] approved under § 803.14'' from §§ 803.13, 803.30, 803.33, 803.40, and 803.53, and updating wording in § 803.20 and 803.56 to be more consistent with the fact that reports will not be submitted on paper (and thus, for example, would no longer have a front and back).

If this proposed rule becomes final, manufacturers, importers, and user facilities would be required to begin submitting medical device reports to the agency in electronic format no later than 1 year from the date of publication of a final rule. After the effective date, the agency would not accept MDRs submitted on paper copies of the FDA Form 3500A, or in electronic formats other than those identified as ones that FDA can process, review, and archive in information provided in conjunction with this rule, unless the agency had granted an exemption or variance as provided for in § 803.19.

1. How Would the Reporting Requirements for Manufacturers Change With Respect to Electronic Format?

The rule would amend §§ 803.50(a), 803.53, and 803.56 to require submission of information required by §§ 803.52, 803.53, and 803.56 in electronic format in accordance with § 803.12(a).

2. How Would the Reporting Requirements for Importers Change With Respect to Electronic Format?

The proposed rule amends § 803.40(a) to require submission to FDA of information required by § 803.42 in electronic format in accordance with § 803.12(a). The proposed electronic format requirement does not extend to importer reports submitted to device manufacturers, which may be in any format that the recipient can read.

3. How Would the Reporting Requirements for User Facilities Change With Respect to Electronic Format, and How Would Annual Report Requirements be Affected?

The proposed rule amends § 803.30(a) to require submission to FDA of information required by § 803.32 in electronic format in accordance with § 803.12(a). The amendment does not impose mandatory electronic format requirements on user facility reports submitted to device manufacturers, which may be provided in any format the recipient can read.

The proposed rule also makes certain changes to § 803.33, addressing user facility annual reports. Under the proposed rule, user facilities will continue to submit annual reports on the paper FDA Form 3419. Because the proposal to require submission of individual adverse events reports in electronic format calls for amendments to § 803.12 and for removal of §§ 803.11 (indicating how to obtain paper forms) and 803.14 (addressing voluntary electronic submissions), FDA is proposing to amend § 803.33 to specify where to obtain the FDA Form 3419, where to submit completed reports under that section, and to remove references to § 803.14.

4. How Would the Requirement to Submit Reports in Electronic Format Affect Recordkeeping Requirements?

Section 803.18 of the regulation addresses requirements for establishing and maintaining MDR files or records for manufacturers, user facilities, and importers. FDA is proposing to amend § 803.18(b)(ii) to require that MDR files contain copies of all reports submitted under part 803, whether paper or electronic. As under the current regulations, under the proposal, regulated entities may choose to maintain required records either in hard copy, by printing out reports submitted in electronic format, or in electronic form. (For information regarding FDA's current thinking and enforcement policy with regard to requirements for maintaining electronic records, see 21 CFR part 11 and the agency guidance document, ''Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf5667fnl.pdf*.). FDA is also proposing to add § 803.18(b)(1)(iii) to require the retention of all acknowledgments FDA sends the manufacturer, importer, or user facility when reports are submitted in electronic format, which will indicate the timing and success of submission.

B. How Would I Submit MDRs in Electronic Format?

As noted previously, if the proposed rule is finalized, manufacturers, importers, and user facilities will be required to submit most MDRs to the agency in an electronic format that FDA can process, review, and archive. In order to best accommodate technological changes, FDA expects to issue information on how to prepare and submit MDRs to the agency in a way that would satisfy the requirements of this proposed rule. The most specific and updated information about how to create, format, and transmit reports, using the CeSub software (designed for low volume reporting) or the HL7 ICSR (designed for high volume reporting), is provided on the agency's Web site, at the address provided in proposed § 803.23. The agency will make every effort to maintain backwards compatibility when implementing changes to the systems and formats for electronic submission. When backwards compatibility is not possible, the agency will provide public notice with a duration commensurate with the complexity of the change.

C. How Can a Medical Device Manufacturer, Importer, or User Facility Obtain a Variance Regarding the Requirement to Submit a Report in Electronic Format?

Under proposed § 803.19, a manufacturer, importer, or user facility may submit a written request to FDA seeking a variance of the § 803.12 requirement to submit reports to the agency in an electronic format that the agency can process, review, and archive. Written requests must contain the reason(s) why the reporting entity requires a variance and for how long the variance is needed. FDA anticipates receiving few variance requests because of the availability of the Internet and the commercial availability of digital certificates as well as FDA's free CeSub Internet software. Under the proposal, if FDA grants a variance, the

manufacturer, importer, or user facility would be required to submit MDRs as specified by FDA in the letter authorizing the variance.

D. What Other Changes Are Being Proposed?

The proposed rule would also codify the following modifications:

1. FDA proposes to remove the definition of ''Five-day report'' in § 803.3, which merely referred to a report submitted under § 803.53 (the only provision of the regulation in which the term appears), using the FDA Form 3500A or ''an electronic equivalent approved under § 803.14.'' Because this definition is not necessary, FDA proposes to remove it.

2. FDA proposes to amend §§ 803.32, 803.42, and 803.52 to make minor wording changes and corrections to these sections to reflect modifications already made to FDA Form 3500A and its instructions, with OMB approval under the PRA. For example, section 303 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) required FDA to modify the forms to facilitate reporting of MDRs involving single-use devices that have been reprocessed for reuse (see 69 FR 7491, February 17, 2004). FDA is proposing to amend §§ 803.32, 803.42, and 803.52 to reflect the addition to the FDA Form 3500A of these two questions concerning whether the device is a single use device that has been reprocessed and reused on a patient and the name and address of the reprocessor.

FDA is also proposing to change §§ 803.32(b)(4), 803.42(b)(4), and 803.52(b)(4) from ''date of report by the initial reporter'' to ''date of this report.'' This change would make part 803 consistent with the way that other FDA Centers interpret FDA Form 3500A, Block B4 and how Block B4 appears on FDA Form 3500A. Finally, FDA is also proposing to make other minor updates to §§ 803.32(c), 803.42(c), and 803.52(c) and (e) to reflect the changes already made to the forms and instructions, including a reference to the product code and PMA/510(k) number.

E. When Would the Rule Become Effective?

FDA proposes that any final rule that issues based on this proposal become effective 1 year after the date the final rule publishes in the **Federal Register**.

III. What Is the Legal Authority for This Rule?

FDA's legal authority to amend its regulations governing the submission of postmarket medical device adverse event reports for medical devices derives from 21 U.S.C. 352, 360, 360i, 360j, 371, and 374.

IV. Is There an 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 impacts of the proposed rule under Executive Order 12866 and 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). This proposed rule has been determined to be a significant regulatory action.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we lack information on the electronic submission capabilities of all the firms potentially affected by this proposed rule we have not proposed to certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. We request commenters to submit such information in their comments.

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 $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that will meet or exceed this amount.

The purpose of this proposed rule is to require the submission of MDRs in an electronic format the agency can process, review, and archive. It would affect all persons subject to medical device reporting under part 803, which includes medical device manufacturers, device importers, and user facilities.

The proposed rule is part of a greater agency initiative to adopt electronic technologies to improve the quality of our operations and increase the efficiency of our resources. The rule would reduce FDA's current costs associated with processing medical device reports (or MDRs) that are received on the paper FDA Form 3500A. By receiving MDRs electronically, FDA would be able to access the adverse event information more quickly and also eliminate potential data entry errors that could occur during input transcription of the information from the paper FDA Form 3500A reports into our electronic medical device adverse event reporting database.

After considering various alternatives, FDA determined that without this regulation, the agency will need to maintain adequate resources to continue to convert paper 3500A MDRs to electronic MDR records until all manufacturers, importers, and user facilities voluntarily adopted the proposed electronic submission format, possibly years in the future.

A. Benefits

The major benefit of this proposed rule would be to public health because the agency would have quicker access to the medical device adverse event reports information and thus could more quickly identify and act on any medical device problems. Currently, FDA receives 100,000 initial MDRs annually on the paper FDA Form 3500A, which are manually entered into the FDA database. FDA receives an additional 110,000 supplemental reports each year that are also submitted on the paper FDA Form 3500A and need to be processed and entered into the FDA database. It can take from 3 days to more than 6 months before an MDR submitted on a paper copy of the FDA Form 3500A may be available for analysis in the Manufacturer and User Device Experience database (MAUDE). With a standardized electronic format, medical device reports would become available for analysis as soon as they are processed into MAUDE. With a reduction in the time to manually enter the MDRs into the MAUDE database, analysis and action, including feedback to manufacturers and consumers, could be taken sooner with a corresponding benefit to public health.

The public health benefits would be supplemented with operating cost reductions within FDA. Assuming the number of MDRs remains fairly constant over time, electronic reporting would

save the agency about $1.25 million annually in data entry costs, which is about one-half of our current data entry contract.

B. Costs

There are about 18,000 medical device manufacturers and importers identified in FDA's medical device registration database and approximately 38,500 user facilities identified in the 2002 U.S. Economic Census that would be affected by the proposed rule (for a total of 56,500 manufacturers, importers, and user facilities) (Census, 2002). Table 1 shows the estimated numbers of firms and establishments in the affected industries.

TABLE 1.—AFFECTED FIRMS AND ESTABLISHMENTS

North American Industry Classification System (NAICS) Code	Description	No. of Firms	No. of Establishments
Various	Devices	18,000	8,000
622	Hospitals	3,800	6,342
6231	Nursing care facilities	7,826	15,480
6214	Outpatient care centers	11,125	23,912
6215	Medical and diagnostic laboratories	5,736	9,844
6216	Home health care services	9,987	15,016
Total		56,474	88,594

The incremental cost of changing to electronic submissions for each affected entity would vary by the size, type, and corporate structure of the firm, as well as by its current electronic submission capability. The total costs associated with this proposed rule would include one-time set-up costs and annual operating costs.

1. One-Time Costs

One-time costs would be the sum of the costs of:

- Rewriting standard operating procedures (SOPs) and training the appropriate personnel,
- Installing and validating either the installation of CDRH's CeSub Web interface software or the programming and configuration of a computer system to transmit reports directly to the FDA ESG using the HL7 ICSR, and
- Acquiring the electronic digital certificate required by the FDA ESG.

a. *Rewriting SOPs and training personnel.* All entities affected would need to update their SOPs to include the electronic submission requirement. For medical device manufacturers, importers, and hospitals, we estimate that it would require about 10 hours to make the modifications and train the appropriate people on the new procedures. For the other user facilities, we assume that the corporate or regional offices would have the major responsibility for medical device reporting and thus the SOPs for these individual entities would require less time to modify. For this analysis we estimated that 55 percent of the other user facilities would require about 10 hours to modify their SOPs and the remaining 45 percent would require about 2 hours.[1] The estimated one-time incremental cost for updating SOPs, assuming an average wage rate of $52 per hour,[2] (Bureau of Labor Statistics (BLS), 2006) is about $34.1 million [((18,000 medical device manufacturers and importers + 6,300 hospitals) x 10 hours) + ((0.45 x 2 hours + 0.55 x 10 hours) x 64,500 other user facilities) x $52/hour].

b. *Setting up systems for submission.* MDRs would be submitted through the FDA ESG using one of two methods: The CDRH CeSub software or the HL7 ICSR. Because most entities are small and submit few if any MDRs annually, we assume they would probably use the CDRH CeSub software, which allows for the submission of one MDR at a time. To comply using this submission method, manufacturers, importers, and user facilities would need high-speed Internet connections and would have to download and install up to three free software programs, validate the installation, and train the appropriate personnel on the new procedures. Entities that have dedicated information technology (IT) staff would be able to install and validate the installation themselves. Smaller manufacturers, importers, and user entities would probably choose to hire an outside contractor for the installation and its validation.

We do not have data on the amount of time required to install and validate the installation of the software or the percentage of entities that might need to contract out the installation. For this analysis, we assumed it would take an entity 8 to 16 hours to install and validate the installation of CDRH's CeSub software and install, if necessary, Java Runtime Edition software and Java security policy files for their Internet browser. This estimate also includes the time required to notify FDA, run a test submission through the FDA ESG, and to train the appropriate staff to use the new program. We are also assuming that almost all medical device manufacturers, importers, and all user facilities would use this method to submit MDRs. Using an average wage of $46.50 for computer and mathematical occupations[3] (BLS 2006), we estimate the cost to install and use the software to be between $21.0 million and $41.7 million [(8 hours x $46.50 wage) x (38,500 user facilities + 18,000 manufacturers and importers) to (16 hours x $46.50 wage) x (38,500 user facilities + 18,000 manufacturers and importers)].

Entities that submit a large number of MDRs each year may choose to use the HL7 ICSR method to submit the reports.

[1] Percentages are based on the ratio of firms to establishments from 2002 Census of Manufactures data.

[2] $52 per hour wage is based on BLS Occupational Employment and Wages, May 2006, for Medical and Health Service Managers, Standard Occupational Classification 11–19111. Forty percent was added to the mean hourly wage of $37.09 to account for benefits and the total was rounded to the nearest whole number.

[3] BLS Occupation Employment and Wages, May 2006, by occupation, for all industries (*http://www.bls.gov*). Wage ($46.50) includes mean hourly wage of $33.22 for Standard Occupational Classification 15–0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits.

This method allows for the batch submission of multiple MDRs at faster transmission rates. We do not know at what threshold of reporting it becomes cost effective for an entity to submit medical device reports using this method. An analysis of FDA submission data for a 6-year period indicated that about 20 large medical device manufacturers submit 500 or more MDRs each year and about 85 submit close to 100 medical device reports per year. We assumed that the actual number of entities using the HL7 ICSR would fall somewhere within this range (20 to 85). We also assumed that only entities that have existing infrastructure to support HL7 ICSR transmissions would choose this method to submit MDRs. We estimated that it would take about 50 hours to set up their gateway to be compatible with the agency's system. Using the wage $46.50, the one-time cost for establishing HL7 ICSR submission capabilities would range between $50 thousand and $200 thousand [($46.50 x 50 hours) x 20 entities) and ($46.50 x 50 hours) x 85 entities)].

c. *Electronic certificates.* All entities would need an electronic certificate to submit any electronic regulatory document to the FDA ESG. The electronic certificate identifies the sender and serves as an electronic signature. Entities that have not submitted any electronic documents to the agency would incur a one-time cost to acquire the certificate and recurring costs to keep the certificate active as a result of this proposed rule. The certificates cost about $20 and are valid for 1 year. We assume that the search and transactions costs involved in the initial acquisition of the certificate doubles the cost of the certificate to a total of $40 for the first year, half of which would be setup costs. If all entities needed to acquire electronic certificates, the one-time search and acquisition costs would be $1.1 million ($20 acquisition cost x 56,500 entities).

In addition to the costs we have estimated, manufacturers, importers, and user facilities affected by this proposed rule may have to hire outside expertise to install and validate the software installation to comply with the proposed requirements.

Table 2 summarizes the estimated one-time costs by type of cost for this proposed rule by cost and type of manufacturers, importers, and user entities. The estimate of the total one-time costs for all manufacturers, importers, and user facilities ranges from $58.6 million to $79.7 million. Much of the cost involves acquiring the electronic certificate for the capability to submit any regulatory document to the FDA, including installation and validation of the CeSub software or to establish HL7 ICSR capabilities. Therefore, manufacturers, importers, and user facilities that are not already making electronic submissions of any kind to the agency if this proposed rule becomes final would incur these total costs.

TABLE 2.—SUMMARY OF ONE-TIME COSTS BY INDUSTRY ($ MILLION)

Industry	Modifying SOPs	Install and validate CeSub software		Gateway to gateway		Acquiring e-certificate	Total	
		low	high	low	high		low	high
Medical Device	9.4	6.7	13.4	0.05	0.2	0.4	16.6	23.4
User Facility	26.9	14.3	28.6			0.8	42.0	56.3
Total	36.3	21.0	42.0	0.05	0.2	1.2	58.6	79.7
Annualized at 3 percent over 10 years							6.9	9.3
Annualized at 7 percent over 10 years							8.3	11.4

2. Annual Costs

The annual costs of this proposed rule would include the costs of:

- Maintaining certificates and
- High-speed Internet access.

a. *Maintaining electronic certificates.* Manufacturers, importers, and user facilities would bear the cost to maintain the electronic certificate that identifies the sender. In addition to having to renew the certificate on a regular basis, those entities who have not submitted MDRs would also have to ensure they are capable of transmitting electronic MDRs to FDA should such a report submission be necessary. To add these costs to the cost of the certificate itself, we assume that entities would incur an additional annually recurring cost equal to one-half the price of the certificate ($10), for a total annually recurring cost of $30. If all manufacturers, importers, and user facilities need to acquire electronic certificates, the annual cost would be $1.7 million ($30 acquisition certificate renewal and acquisition cost x 56,500 entities).

b. *High-speed Internet access.* Entities would also need high-speed Internet access to use either of the submission methods. A 2004 study of small businesses sponsored by the Small Business Administration (SBA) found that essentially all small firms had Internet access and about 50 percent had high-speed Internet access (Pociask, 2004). The average cost of high speed access was about $40 per month more than dial-up access. Because the average cost of Internet access has been going down over time, we estimate that by the time this proposed rule would be made final, about 75 percent of device and user facilities would have high speed access. The average annual recurring increase in cost for high speed Internet access for the remaining 25 percent of the entities would be $6.8 million (($40 x 12 months) x (0.25 x (18,000 manufacturers and importers + 38,500 user facilities))).

Table 3 shows the annual costs of the proposed rule. As with the one-time costs, only entities not making electronic regulatory document submissions of any kind to the agency if this proposed rule becomes final would incur all these costs. There would be no change in the actual time required to research and prepare the MDRs, nor would there be any additional reporting requirements as a result of this proposed rule. Manufacturers, importers, and user facilities that maintain paper FDA Form 3500A records for their internal MDR files own use could still do so under the proposed rule.

TABLE 3.—SUMMARY OF ANNUAL COSTS BY INDUSTRY ($ MILLION)

Industry	Acquiring electronic certificate	High-speed Internet access	Total
Medical Device	0.5	2.2	
User Facility	1.2	4.6	
Total	1.7	6.8	8.5

Cost savings: We estimate a modest industry savings of about $3.2 million annually because electronic submission should reduce the time it takes to submit documents. It should be noted that the savings accumulate to firms submitting MDRs; firms that submit very few or no MDRs would not realize any savings.

C. Summary of Benefits and Costs

The principal benefit of this proposed rule would be the public health benefits associated with more rapid processing and analysis of the 100,000 initial individual MDRs currently submitted to FDA on a paper FDA Form 3500A. In addition, requiring electronic submission of MDRs is expected to reduce FDA annual operating costs by $1.25 million and generate industry savings of about $3.2 million.

The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from $58.6 million to $79.7 million. Annually recurring costs totaled $8.5 million and include maintenance of electronic submission capabilities, including renewing the electronic certificate, and for some entities the incremental cost to maintain high-speed Internet access. The total annualized cost of the proposed rule, assuming a 7-percent discount rate over 10 years, would be from $16.8 million to $19.9 million ($15.4 million to $17.8 million at a 3-percent discount rate). We request comment on the accuracy and completeness of the assumptions used to estimate the costs of this proposed rule. For example, we invite comment on our use of a 10-year time horizon and whether a shorter or a longer horizon would be more appropriate to express the social costs of this proposed rule.

D. Alternatives Considered

During the development of this proposed rule, we considered a number of alternative approaches. The first was to allow manufacturers, importers, and user facilities to voluntarily submit MDRs electronically. Because our experience has shown that a number of medical device firms and user facilities would resist changing their procedures for a long period of time, we would not attain the benefits of standardized formats and quicker access to medical device adverse event data. The FDA, for example, would have to maintain contracts to handle the input of information from both written and electronic MDRs. A voluntary system, therefore, would fail to achieve the goals of this proposed rule.

Another alternative was to allow small entities more time to comply with the electronic submission requirements. This alternative would allow small entities to delay compliance. Under this alternative, we would not receive the full data-entry savings from requiring electronic submissions or all the benefits of quicker access to these reports. Because so many device companies are small entities, this approach would significantly postpone the benefits the rule is intended to confer. Moreover, as shown in the following section, the estimated incremental costs per small entity from the proposed rule are small, so the cost reduction per small entity from delayed compliance would also be small.

E. Regulatory Flexibility Analysis

The SBA defines a small medical device manufacturer as having fewer than 500 employees. Based on data from U.S. Census, about 98 percent of device firms affected by this proposed rule are considered small entities, and have an average value of shipments of about $9.0 million.[4] Businesses in the health care industry are classified as small if their revenues are below a certain level. Hospitals are small if their total revenue falls below $25 million and the other user facilities are considered small if their revenues are below $10 million. U.S. Census data indicates that about 87 percent of the user facilities are classified as small and have a weighted average revenue of about $3.3 million.[5] However, very few user facilities submit MDRs in any given year. While this proposed rule will now require those reports submitted to the agency to be in electronic format, the content of a report is not being changed from that already addressed on the current FDA Form 3500A. The average costs for these manufacturers, importers, and user facilities are listed in table 4. The average total annualized cost per small entity, assuming a 7-percent discount rate over 10 years, would range from $581 to $693; at a 3-percent discount rate, average annualized costs would range from $568 to $661. These costs represent less than 0.1 percent of revenues for medical device firms and less than 0.1 percent of revenues for user facilities.

We considered two possible alternatives for regulatory relief for small businesses. As described above, one regulatory alternative would be longer compliance times for small entities. We would not receive the full data-entry savings from requiring electronic submissions or all the benefits of quicker access to these reports. Because so many device companies are small entities, this approach would significantly postpone the benefits the rule is intended to confer. Moreover, as shown above, the estimated incremental costs per small entity from the proposed rule are small, so the cost reduction per small entity from delayed compliance would also be small.

In addition, we considered proposing a waiver to the electronic submission requirement for small firms that can demonstrate an economic hardship. Because the estimated incremental costs per small entity from the proposed rule are small, the cost reduction per small entity from a waiver would also be small.

We ask for comments on both of these options for regulatory relief for small entities.

While the estimated costs per affected entity are low, FDA does not have adequate information on the electronic capabilities of all of the firms affected

[4] U.S. Census Bureau, 2002 Economic Census, Manufacturing Industry Series, Industry Statistics by Employment Size for NAICS codes: 334510, 339112, 339113, 339114, and 339115 (*www.census.gov*).

[5] U.S. Census Bureau, 2002 Economic Census, Release Date 11/22/2005, Sector 62: Health Care and Social Assistance: Subject Series—Establishment and Firm Size: Receipts/Revenue Size the United States for NAICS 622, 6231, 6214, 6215, and 6216 accessed via American Fact Finder (*www.census.gov*).

by this proposed rule and has made many assumptions to derive these estimate used in this analysis, therefore we do not propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities. FDA requests comment on this issue.

TABLE 4.—INCREMENTAL COMPLIANCE COSTS PER SMALL ENTITY

	One-Time Costs		Annually Recurring	Total Annualized	
	low	high		low	high
Rewriting SOPs	104	520			
Software Installation and validation of installation	372	744			
Acquiring Electronic Certificate	40				
Maintaining submission capabilities			30		
Upgrade Internet Access			480		
7 percent discount rate				581	693
3 percent discount rate				568	661

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given in this document 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 these topics: (1) Whether the proposed collection of information is necessary for the proper 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: Medical Device Reporting

Description: In accordance with the proposed Medical Device Reporting regulation, medical device manufacturers, importers, and user facilities would be required to submit MDRs to FDA, to maintain records, and may also seek exemption or variance from these requirements. FDA is also proposing to amend §§ 803.32, 803.42, and 803.52 to make minor wording changes and corrections to these sections to reflect modifications already made to FDA Form 3500A and its instructions. Manufacturers, importer, and user facilities are currently submitting paper MDR reports on FDA Form 3500A. The existing information collection for part 803 is approved under OMB control number 0910–0437. The changes to the burden associated with this proposed rule are described below and have been sent to OMB as a revision to OMB control number 0910–0437 for review under section 307(d) of the PRA.

Section 519(a)(1) of the act (21 U.S.C. 360i(a)(1)) requires every manufacturer or importer to report ''whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur * * *''

Section 519(b)(1)(A) of the act requires ''whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device.''

Section 519(b)(1)(B) of the act requires ''whenever a device user facility receives or otherwise becomes aware of: (i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility * * *, shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.''

Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems so the agency can protect the public health under section 519 of the act. FDA is requesting approval for the information collection requirements contained in part 803.

Description of Respondents: Manufacturers and importers of medical devices and device user facilities. Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in § 803.3, which is not a physician's office (also defined in § 803.3).

The total annual estimated burden imposed by this collection of information is 21,525 hours annually.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
803.19		55	4	220	1	220
803.30 and 809.32		411	2	822	0.33	271
803.33	3419	411	1	411	1	411
803.40 and 803.42		44	20	880	0.33	290
803.50 and 803.52		1,304	58	75,632	0.11	8,248
803.56		1,200	48	57,600	0.10	5,760
Total						15,200

TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Respondents	Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
803.17	1,677	1	1,677	3.3	5,534
803.18 (a) to (d)	527	1	527	1.5	791
Total	2,204		2,204		6,325

The approved MDR reporting and recordkeeping burden for paper submissions is 138,271 hours. This proposed rule reporting and recordkeeping burden for electronic submissions is 21,525 hours, a decrease of 123,071 hours. Based on an average wage rate of $46.50 per hour, the total cost to respondents associated with these reporting and recordkeeping burdens is $1,000,913. An explanation for the burden decrease is provided below.

A. Reporting Requirements

The number of respondents for each Code of Federal Regulations (CFR) section in table 5 is based upon the number of respondents entered into FDA's internal databases. FDA estimates that electronic submission will decrease the burden associated with §§ 803.19, 803.30, 803.32, 803.40, 803.50, 803.52, and 803.56. We believe electronic submission will neither increase nor decrease burden associated with § 803.33, which we estimate will take 1 hour. We believe § 803.19 will take 1 hour, while §§ 803.30, 803.32, 803.40, and 803.42 will take 20 minutes. Sections 803.50 and 803.52 will take 7 minutes. Section 803.56 will take 6 minutes. The following table summarizes our burden estimates and how we believe they will change due to electronic submission.

TABLE 7.—ESTIMATED REPORTING BURDEN PROGRAM CHANGE

21 CFR Section	Hours per response under current paper submission process	Hours per response as result of electronic submission	Burden Change
803.19	3	1	Reduction (2 hours)
803.30 and 809.32	1	0.33	Reduction (.66 hours)
803.33	1	1	no change
803.40 and 803.42	1	0.33	Reduction (.66 hours)
803.50 and 803.52	1	0.11	Reduction (.89 hours)
803.56	1	0.10	Reduction (.90 hours)

As previously described, there are two reporting options. The first one is CeSub for low volume reporters and the second one is HL7 ICSR for high volume reporters. We are basing our hours per response for both systems on FDA's experience using the two options.

B. Recordkeeping Requirements

The number of respondents for each CFR section in table 6 is based upon the number of respondents entered into FDA's internal databases. The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. The following table summarizes our burden estimates and how we believe they will change due to electronic submission.

TABLE 8.—ESTIMATED RECORDKEEPING BURDEN PROGRAM CHANGE

21 CFR Section	Hours per response under current paper submission process	Hours per response as result of electronic submission	Burden Change
803.17	10	3.3	Reduction (7.7 hours)
803.18 (a) to (d)	1.5	1.5	No change

C. Total Annual Cost Burden

As stated earlier, the cost to respondents for these reporting and recordkeeping requirements is $1,000,913. In addition, the conversion from paper to electronic submissions will result in capital costs, both one-time costs as well as annual costs, as discussed earlier in this proposed rule in the economic analysis. One-time capital costs include the cost to modify reporting systems, installing and validating CeSub software, installing gateway to gateway submission capabilities, and acquiring e-certificates and have been estimated to range from a low of $58.6 million to a high of $79.7 million. Once the procedures have been modified, there is an operating and maintenance cost to renew the digital certificate and maintain high-speed internet access, which have been estimated cost $8.5 million each year. Burden estimates are based on reports processed between July 1, 2005, and June 30, 2006, with the existing medical device adverse event reporting program.

In compliance with the PRA, the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see the **DATES** and **ADDRESSES** sections of this document).

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that this rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Request for Comments

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.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. U.S. Census Bureau, 2002 Economic Census Industry Series: NAICS Code 62, Health Care and Social Assistance (*http://www.census.gov*). Total is the sum of firms in NAICS 622, 6231, 6214, 6215, and 6216.

2. BLS Occupational Employment and Wages May 2005 for Medical and Health Service Managers, Standard Occupational Classification, 11–19111.

3. Pociask, Steven, A Survey of Small Businesses' Telecommunications Use and Spending, SBA Office of Advocacy contract number SBA–HQ–02–M–0493, March 2004.

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, FDA proposes to amend part 803 to read 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.

§ 803.3 [Amended]

2. Amend § 803.3 by removing the definition for ''Five-day report''.

§ 803.11 [Removed]

3. Remove § 803.11.

4. Revise § 803.12 to read as follows:

§ 803.12 How do I submit reports and supplements?

(a) Manufacturers, user facilities, and importers must submit initial and supplemental reports to FDA in an electronic format that FDA can process, review, and archive. FDA will provide and update information on how to provide the electronic submission (e.g., preparation and organization of files, file formats, media and method of transmission).

(b) If you are confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Office of Emergency Operations (HFA–615), Office of Crisis Management, Office of the Commissioner, at 301–443–1240, followed by the submission of an e-mail to *emergency.operations@fda.hhs.gov*. Note: This action does not satisfy your obligation to report under part 803.

(c) You may submit a voluntary telephone report to the MEDWATCH office at 800–FDA–1088. You may also obtain information regarding voluntary reporting from the MEDWATCH office at 800–FDA–1088. You may also find the voluntary MEDWATCH 3500 form and instructions to complete it at *http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm*.

5. Revise § 803.13 to read as follows:

§ 803.13 Do I need to submit reports in English?

Yes. You must submit all reports required by this part in English.

§ 803.14 [Removed]

6. Remove § 803.14.

7. Amend § 803.18 by revising paragraph (b)(1)(ii) and adding paragraph (b)(1)(iii) to read as follows:

§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

* * * * *

(b)(1) * * *

(ii) Copies of all reports submitted under this part (whether paper or electronic), and of all other information related to the event that you submitted to us or other entities such as an importer, distributor, or manufacturer.

(iii) Copies of all electronic acknowledgments FDA sends you in response to your electronic submissions.

* * * * *

8. Amend § 803.19 by revising paragraphs (b) and (e) to read as follows:

§ 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

* * * * *

(b) If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this part, including the requirements of § 803.12(a). You must submit the request to us in writing at the following address: MDR Exemption Requests, Office of Surveillance and Biometrics (HFZ–530), 1350 Piccard Dr., Rockville, MD 20850. Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified. If you are requesting a variance to the requirement to submit reports to FDA in electronic format, under § 803.12(a), your request should indicate for how long you would require this variance.

* * * * *

(e) If we grant your request for a reporting modification, you must submit any reports or information required in our approval of the modification. The conditions of the approval will replace and supersede the regular reporting requirement specified in this part until such time that we revoke or modify the alternative reporting requirements in accordance with paragraph (d) of this section, or until the date specified in our response granting your variance, at which time, the provisions of this part will again apply.

9. In § 803.20, revise paragraph (a), redesignate paragraphs (b) and (c) as paragraphs (c) and (d), and add new paragraph (b) to read as follows:

§ 803.20 How do I complete and submit an individual adverse event report?

(a) If you are a health professional or consumer, you may submit voluntary reports to FDA regarding devices or other FDA-regulated products using the FDA Form 3500.

(b) A mandatory electronic submission from a user facility, importer, or manufacturer, must contain the information from the applicable blocks of FDA Form 3500A. All electronic submissions must include information about the patient, the event, the device, and the ''initial reporter.'' An electronic submission from a user facility or importer must include the information from block F. An electronic submission from a manufacturer must include the information from blocks G and H. If you are a manufacturer and you receive a report from a user facility or importer, you must incorporate that information in your electronic submission and include any corrected or missing information.

* * * * *

10. Add § 803.23 to read as follows:

§ 803.23 Where can I find information on how to prepare and submit an MDR in electronic format?

(a) You may obtain information on how to prepare and submit reports in an electronic format that FDA can process, review, and archive at *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm*.

(b) We may sometimes update information on how to prepare and submit reports electronically. If we do make modifications, we will ensure that we alert reporters by updating the eMDR Web page.

11. Amend § 803.30 by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 803.30 If I am a user facility, what reporting requirements apply to me?

(a) * * *

(1) *Reports of death*. You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. You must also submit the report to the device manufacturer, if known. You must submit the information required by § 803.32. Reports sent to the agency must be submitted in accordance with the requirements of § 803.12(a).

(2) *Reports of serious injury*. You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by § 803.32. Reports sent to the agency must be submitted in accordance with the requirements of § 803.12(a).

* * * * *

12. Amend § 803.32 by revising paragraphs (b)(4) and (c) to read as follows:

§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

* * * * *

(b) * * *

(4) Date of this report;

* * * * *

(c) Device information (Form 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Product Code, if known, and Common Device Name;

(3) Manufacturer name, city, and state;

(4) Model number, catalog number, serial number, lot number, or other identifying number, and expiration date;

(5) Operator of the device (health professional, lay user/ patient, other);

(6) Date of device implantation (month, day, year), if applicable;

(7) Date of device explantation (month, day, year), if applicable;

(8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)?

(9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;

(10) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

* * * * *

13. Revise § 803.33 to read as follows:

§ 803.33 If I am a user facility, what must I include when I submit an annual report?

(a) You must submit to us an annual report on FDA Form 3419. You must submit an annual report by January 1, of each year. You may obtain this form from any of the following:

(1) The Consolidated Forms and Publications Office, Beltsville Service Center, 6351 Ammendale Rd., Landover, MD 20705;

(2) FDA, MEDWATCH (HF–2), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7240;

(3) Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH) (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, by e-mail: *DSMICA@CDRH.FDA.GOV*, or FAX: 301–443–8818; or

(4) On the Internet at *http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm*.

(b) You must clearly identify your annual report as such. You must submit your annual report to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002. Your annual report must include:

(1) Your CMS provider number used for medical device reports, or the number assigned by us for reporting purposes in accordance with § 803.3;

(2) Reporting year;

(3) Your name and complete address;

(4) Total number of reports attached or summarized;

(5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890–2007–0001 through 1000);

(6) Name, position title, and complete address of the individual designated as your contact person responsible for reporting to us and whether that person is a new contact for you; and

(7) Information for each reportable event that occurred during the annual reporting period including:

(i) Report number;

(ii) Name and address of the device manufacturer;

(iii) Device brand name and common name;

(iv) Product model, catalog, serial and lot number;

(v) A brief description of the event reported to the manufacturer and/or us; and

(vi) Where the report was submitted, i.e., to the manufacturer, importer, or us.

(c) In lieu of submitting the information in paragraph (b)(7) of this section, you may submit a copy of each medical device report that you submitted to the manufacturers and/or to us during the reporting period.

(d) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.

14. Revise § 803.40 to read as follows:

§ 803.40 If I am an importer, what reporting requirements apply to me?

(a) *Reports of deaths or serious injuries.* You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable, but no later than 30 calendar days after the day that you receive or otherwise become 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 your marketed devices may have caused or contributed to a death or serious injury. You must submit the information required by § 803.42. Reports must be submitted in accordance with the requirements of § 803.12(a).

(b) *Reports of malfunctions.* You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests that one of your devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. You must submit the information required by § 803.42.

15. Amend § 803.42 by revising paragraphs (b)(4) and (c) to read as follows:

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

* * * * *

(b) * * *

(4) Date of this report;

* * * * *

(c) Device information (Form 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Product Code, if known, and Common Device Name;

(3) Manufacturer name, city, and state;

(4) Model number, catalog number, serial number, lot number, or other identifying number, and expiration date;

(5) Operator of the device (health professional, lay user/patient, other);

(6) Date of device implantation (month, day, year), if applicable;

(7) Date of device explantation (month, day, year), if applicable;

(8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)?

(9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;

(10) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

* * * * *

16. Amend § 803.50 by revising paragraph (a) introductory text and paragraph (b)(3) to read as follows:

§ 803.50 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us the information required by § 803.52 in accordance with the requirements of § 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:

* * * * *

(b) * * *

(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56 in accordance with the requirements of § 803.12(a).

17. Amend § 803.52 by revising paragraphs (b)(4), (c), and (e) to read as follows:

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

* * * * *

(b) * * *

(4) Date of this report;

* * * * *

(c) Device information (Form 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Product code, if known, and Common Device Name;

(3) Manufacturer name, city, and state;

(4) Model number, catalog number, serial number, lot number, or other identifying number, and expiration date;

(5) Operator of the device (health professional, lay user/patient, other);

(6) Date of device implantation (month, day, year), if applicable;

(7) Date of device explantation (month, day, year), if applicable;

(8) Whether the device is a single-use device that was reprocessed and reused on a patient (Yes, No)?

(9) If the device is a single-use device that was reprocessed and reused on a patient (yes to paragraph (c)(8) of this section), the name and address of the reprocessor;

(10) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(11) Concomitant medical products and therapy dates. (Do not report products that were used to treat the event.)

* * * * *

(e) Reporting information for all manufacturers (Form 3500A, Block G). You must submit the following:

(1) Your reporting office's contact name and address and device manufacturing site;

(2) The contact's telephone number;

(3) Your report sources;

(4) Date received by you (month, day, year);

(5) PMA/510k Number and whether or not the product is a combination product;

(6) Type of report being submitted (e.g., 5–day, initial, followup); and

(7) Your report number.

* * * * *

18. Revise the introductory text of § 803.53 to read as follows:

§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

You must submit a 5-day report to us with the information required by § 803.52 in accordance with the requirements of § 803.12(a) no later than 5 work days after the day that you become aware that:

* * * * *

19. Amend § 803.56 by revising the introductory text and paragraphs (a) and (c) to read as follows:

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 30 calendar days of the day that you receive this information. You must submit the supplemental or followup report in accordance with the requirements of § 803.12(a). On a supplemental or followup report, you must:

(a) Indicate that the report being submitted is a supplemental or followup report;

* * * * *

(c) Include only the new, changed, or corrected information.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19683 Filed 8–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–331]

Schedules of Controlled Substances: Placement of 5-Methoxy-N,N-Dimethyltryptamine Into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of proposed rulemaking to place the substance 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) and its salts into schedule I of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. If finalized as proposed, this action would impose the criminal sanctions and regulatory controls of schedule I substances under the CSA on the manufacture, distribution, dispensing, importation, exportation, and possession of 5-MeO-DMT.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before September 21, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–331'' on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing Microsoft Word, WordPerfect, Adobe PDF, or Excel files only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Comments and Requests for Hearing

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557). All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested persons and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may request a hearing.

21 CFR 1308.42. Please note that DEA may grant a hearing only ''for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable'' pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug