

(iii) *Normal living tissue*. The allergic hypersensitivity reaction occurs in normal living tissues, including the skin, mucous membranes (*e.g.*, ocular, oral), and other organ systems, such as the respiratory tract and gastrointestinal tract, either singularly or in combination, following sensitization by contact, ingestion, or inhalation.

* * * * *

Dated: February 11, 2014.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its postmarket medical device reporting regulation and making technical corrections. This final rule requires device manufacturers and importers to 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 will improve the Agency's process for collecting and analyzing postmarket medical device adverse event information. Electronic reporting is also available to user facilities, but this rule permits user facilities to continue to submit written reports to FDA. This final rule also identifies changes to the content of required MDRs to reflect reprocessor information collected on the Form FDA 3500A as required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: This final rule is effective August 14, 2015 (see also section IX of this document).

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I. History of the Medical Device Reporting Regulation

The MDR regulation was first published on September 14, 1984 (49 FR 36326), with requirements for manufacturer and importer reporting of deaths, serious injuries, and

malfunctions effective December 13, 1984.¹ FDA's regulations governing medical device adverse event reporting implement section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i). Section 519 of the FD&C Act has undergone several changes since its enactment as part of the Medical Device Amendments of 1976 (Pub. L. 94-295). As a result, FDA's regulations at part 803 (21 CFR part 803) have also undergone multiple revisions. The Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629) amended the FD&C Act to require mandatory reporting of device adverse events by user facilities (deaths reported to FDA and the manufacturer, and serious injuries or illnesses reported to the manufacturer) and domestic distributors (deaths and serious injuries or illnesses reported to FDA and the manufacturer, and certain malfunctions reported to the manufacturer). The SMDA also amended the FD&C Act to require manufacturers and distributors (including importers) to certify the number of MDRs submitted to the Agency each year and to require user facilities to submit a semiannual report summarizing reportable events. FDA published a tentative final rule on November 26, 1991 (56 FR 60024), to implement the SMDA requirements for reporting for device manufacturers, user facilities, and distributors, including importers (the 1991 tentative final rule). By statute, user facility reporting became effective on November 28, 1991, and distributor reporting became effective on May 28, 1992.

On June 16, 1992, the Medical Device Amendments of 1992 (the 1992 amendments) (Pub. L. 102-300) further amended certain provisions of section 519 of the FD&C Act relating to reporting of adverse device events. The amendments adopted a single reporting standard and definition for serious injury/serious illness for manufacturers, importers, distributors, and user facilities. The changes under the 1992 amendments were effective on June 16, 1993.

On September 1, 1993, FDA published a final rule (58 FR 46514) that collected the requirements for all wholesale distributors, importers as well as domestic, under a new part 804 (21 CFR part 804).

On December 11, 1995 (60 FR 63578), FDA published a final rule for manufacturers and user facilities (the 1995 final rule), with changes from the 1991 tentative final rule, including a requirement for the use of the Form

¹ See 49 FR 36644, September 19, 1984 (correcting the effective date).

FDA 3500A for reporting. The proposed effective date of April 11, 1996, for the 1995 final rule was extended to July 31, 1996 (61 FR 16043, April 11, 1996).

On November 21, 1997, the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) was enacted. FDAMA made changes regarding the reporting of adverse experiences related to devices, including a stay of the requirement for Annual Certification by manufacturers and distributors, elimination of the requirements for adverse event reporting by domestic distributors, and a change from semiannual reports to annual reports for user facility summary reports. On May 12, 1998, FDA published a direct final rule (63 FR 26069) and a companion proposed rule (63 FR 26129) to implement these changes to the MDR requirements, which included transferring distributor requirements back to part 803. FDA received significant adverse comments on the direct final rule and companion proposed rule; therefore, FDA withdrew the direct final rule and published a revised final rule in the **Federal Register** of January 26, 2000 (65 FR 4112). Under the FD&C Act as amended by FDAMA, distributors who were not importers were no longer required to report adverse events but were still required to keep records. Importers were still required to report adverse events related to medical devices. Because of FDAMA's changes, FDA revised part 803 and removed part 804.

On February 28, 2005, FDA revised the MDR regulation (70 FR 9516) by adopting plain language to make the requirements easier to understand (the 2005 plain language MDR direct final rule).

On June 13, 2008, FDA published a direct final rule (73 FR 33692), and a companion proposed rule (73 FR 33749) to remove the requirement for baseline reports, which were determined largely to duplicate information provided in individual adverse event reports. On September 17, 2008, FDA published a notice (73 FR 53686) confirming the effective date for the direct final rule as October 27, 2008.

On August 21, 2009, FDA published a proposed rule (74 FR 42203) to amend part 803 to require manufacturers, importers, and user facilities to submit MDRs to the Agency in an electronic format (the 2009 proposed rule). The 2009 proposed rule is now being finalized, subject to certain revisions. Because of concerns over the cost of implementation for user facilities, and the relatively low volume of reports FDA receives from such facilities, the final rule does not require user facilities

to adopt electronic reporting. FDA believes that the benefits of this rule can be achieved without applying the electronic reporting requirement to user facilities. Although FDA encourages user facilities to file reports electronically, they may continue to use paper forms for reporting. The rule revises references to the use of paper forms for reporting and makes electronic reporting mandatory for manufacturers and importers. Additionally, the rule modifies the existing regulation to list information for reprocessed single use devices, in order to reflect changes already made to the Form FDA 3500A, in accordance with MDUFMA (Pub. L. 107–250).

II. Overview of the Final Rule

A. Changes to the 2009 Proposed Rule

The 2009 proposed rule included only the parts of the regulation that contained amended and changed language. The final rule contains part 803 in its entirety for ease of reading and clarity.

The 2009 proposed rule proposed to remove the definition for “Five-day report” from § 803.3 as unnecessary since it merely referred to a report under § 803.53. Because there is still a requirement for 5-day reports, we have concluded that removing the definition could be confusing to reporting entities and have decided to retain the definition.

The 2005 plain language MDR direct final rule removed the enumeration of definitions under § 803.3. Subsequent difficulties when referencing specific definitions have suggested that we should reinstitute numbering the definitions and have done so in this final rule.

Certain terminology used in the proposed rule has changed in the final rule. References to CeSub (CDRH eSubmitter) have been revised to reflect the current FDA-wide term used for electronic submissions, eSubmitter.

In addition, under this final rule, a manufacturer or importer needs to request and obtain an exemption from electronic reporting to continue to report via hardcopy past the effective date for electronic reporting. The 2009 proposed rule used the term “variance” at the end of section § 803.19(b), but we have concluded that “exemption” more accurately describes the reporting change and have therefore used the term “exemption” in the final rule. FDA's existing guidance for requesting exemptions applies to such requests.

Technical changes to § 803.11 provide the updated sources for Form FDA 3500A.

Technical changes to § 803.12 update the contact information for the FDA/Office of Crisis Management when reporting a public health emergency and conform language to other sections of the rule.

A change was made to § 803.18(b)(1)(iii) to add the word MDR to clarify the record retention requirement.

Technical changes to § 803.19 update the contact information for the FDA/CDRH/Office of Surveillance and Biometrics when submitting an MDR Exemption Request.

A change was made to § 803.20(c)(2)(ii) to correct an error, such that “30 days calendar” in paragraph (b)(2)(ii) of the current rule was revised as “30 calendar days” in what is now paragraph (c)(2)(ii).

Technical changes to § 803.21 provide the current Web site addresses for obtaining adverse event reporting codes information. This part also provides the current contact information for the FDA/CDRH/Division of Small Manufacturers, International, and Consumer Assistance (DSMICA).

Technical changes to § 803.33 provide the updated sources for Form FDA 3419.

B. Highlights of the Final Rule

For over 20 years, FDA received postmarket MDRs in a paper format through the mail. In 2008, FDA permitted manufacturers to submit postmarket MDRs electronically, on a voluntary basis. This final rule to require the electronic submission to FDA of manufacturer and importer MDRs is an important step toward improving the Agency's systems for collecting and analyzing postmarket MDRs. When manufacturers and importers submit data elements to FDA in a paper format, the information must be manually entered into our internal electronic database before it can be effectively reviewed and analyzed. Under the proposed rule, this data entry will be performed by the manufacturers and importers and they will save the cost of submitting the paper forms. More importantly, eliminating that step will make the information available more quickly to FDA.

This final 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 as well as information that must be reported to FDA in supplemental or followup reports. It does not change the underlying reporting requirements, just the manner in which they are submitted to FDA. This final rule will have the following benefits:

- Reducing industry's time and costs associated with transcribing data from internal data management systems to paper and mailing the paper reports to the Agency;

- Reducing the Agency's transcription errors, time, and costs associated with receiving paper reports and transcribing data to electronic format for review and analysis;

- Expediting the Agency's access to safety information in a format that supports efficient and comprehensive data analysis and reviews; and

- Enhancing the Agency's ability to rapidly communicate information about suspected problems to the medical device industry, health care providers, consumers, and other government Agencies.

C. How do I submit MDRs in electronic format?

Upon the effective date of this final rule, manufacturers and importers are required to submit MDRs to the Agency in an electronic format that FDA can process, review, and archive. The most specific and updated information about how to create, format, and transmit reports electronically using the eSubmitter software (for low volume reporting) or the Health Level 7 Individual Case Safety Reports (HL7 ICSR) (for high volume reporting), is provided on the Agency's Web site at the address identified in the new § 803.23. FDA is committed to providing industry with adequate notice of any specifications changes. To the extent possible, FDA will ensure previous versions of such specifications can still be utilized to submit adverse events electronically.

1. What are the options for electronic reporting?

FDA's CDRH has an MDR database that supports two options for electronic submission of MDRs: One allows the submission of a single report at a time and one allows submission of batches of reports.

a. eSubmitter. The Agency developed software (originally referred to as CeSub or CDRH eSubmitter) that allows for the submission of one MDR at a time. The software allows users to:

- Save address and contact information,
- Search for a Product Code,
- Search for a Patient Problem Code or Device Problem Code,
- Search for Manufacturer Evaluation Codes (method, result, and conclusion codes),
- Attach documents when additional information needs to be provided, and

- 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 Form FDA 3500A, which can be submitted to FDA using the FDA Electronic Submission Gateway (ESG). The final eSubmitter-generated report can also be saved or printed for recordkeeping or to provide reports to manufacturers or other entities outside of FDA. The eSubmitter software and instructions for installation are free and available at: <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>. FDA may make minor changes to the submission format for maintenance purposes as needed to improve the eSubmitter reporting experience.

b. HL7. Reporters with large numbers of MDRs to report, or those that otherwise want to submit reports in batches, may prefer the second option, called the 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 of information directly from the reporter's database to populate an MDR, production of the appropriate data output, and transmission of the MDR to the FDA ESG. In addition, 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 want to consider building functions for saving or printing those reports and for attaching documents, such as photos or labeling, to their records.

Additional information is also available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR-ElectronicMedicalDeviceReporting/default.htm>.

2. What is the FDA ESG?

Both eSubmitter and HL7 reporting options transmit MDRs to FDA using the FDA ESG, a secure entry point for all electronic submissions to the Agency. 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 the FDA ESG and digital certificates is available 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. Each acknowledgement indicates successful completion of a different processing and validation stage for the MDR report and is needed for diagnostic purposes. Acknowledgment 1 comes from the FDA ESG and indicates your submission was received at the FDA ESG. Acknowledgment 2 also comes from the FDA ESG and indicates the submission reached CDRH. Acknowledgment 3, sent by CDRH through the FDA ESG, notifies you that your submission was either successfully loaded into CDRH's adverse event database or that your submission contained errors (specified in the Acknowledgment) that were identified during validation and loading. If there are no errors, we anticipate that the three acknowledgment letters will be generated the same day or within 24 hours of the submission. If there were errors, you need to correct the errors and resend the corrected report in order for your submission to be accepted and loaded into the database.

4. How can I obtain an exemption from the requirement to submit a report in electronic format?

Under § 803.19, a manufacturer or importer may submit a written request to FDA seeking an exemption from the § 803.12(a) requirement to submit reports to the Agency in an electronic format that the Agency can process, review, and archive. The written request for exemption from electronic format must comply with the requirements of § 803.19(b), as well as provide an explanation of why the request is justified, including, with appropriate justification, financial hardship, and a statement of how long the exemption is needed. FDA anticipates receiving few exemption requests relating to the electronic reporting requirement because of the availability of the Internet, the commercial availability of digital certificates, and free access to FDA's eSubmitter Internet software. If FDA grants such an exemption, the manufacturer or importer would be allowed to submit written MDRs for the period of time specified by FDA in the letter authorizing the exemption.

D. How have the MDR requirements changed?

1. What has changed for user facilities and has annual reporting been affected?

Section 803.30(a) requires user facilities to report information required by § 803.32 in accordance with § 803.12(b). User facility reports submitted to device manufacturers may also be in paper format or an electronic format that includes all required data fields to ensure that the manufacturer has all required information. Since user facilities will continue to submit annual reports on the paper Form FDA 3419, the rule amends § 803.33 to specify where to obtain the Form FDA 3419 and where to submit completed annual reports.

2. What has changed for importers?

The 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 mandatory electronic format requirement does not apply to importer reports submitted to device manufacturers, which may be in paper format or an electronic format that includes all required data fields to ensure that the manufacturer has all required information.

3. What has changed for manufacturers?

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

4. Are there changes for recordkeeping?

Section 803.18 contains requirements for establishing and maintaining MDR files or records for manufacturers, user facilities, and importers. The rule amends § 803.18(b)(1)(ii) to require keeping copies of all reports submitted under part 803, whether paper or electronic. (Regulated entities may choose to maintain required records, including copies of all reports, either in hardcopy or in electronic form). We also are adding § 803.18(b)(1)(iii), to require the retention of all acknowledgments that FDA sends the manufacturer, importer, or user facility in response to electronic MDR submissions.

5. What other changes are in this final rule?

The final rule does the following:

- Amends §§ 803.32, 803.42, and 803.52 to reflect the addition to the Form FDA 3500A of a question whether the device is a single use device that has been reprocessed and reused on a

patient and, if so, asking for the name and address of the reprocessor (these modifications were already made to Form FDA 3500A and its instructions, with Office of Management and Budget (OMB) approval under the Paperwork Reduction Act (PRA));

- Changes language in §§ 803.32(b)(4), 803.42(b)(4), and 803.52(b)(4) from “date of report by the initial reporter” to “[d]ate of this report,” to make part 803 consistent with the way that other FDA Centers interpret Form FDA 3500A, Block B4, and how Block B4 appears on Form FDA 3500A; and

- Makes 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 references to the Product Code and PMA/510(k) number.

III. Comments on the Proposed Rule

A. General

The Agency received 35 comments on the 2009 proposed rule. Some comments expressed concern about the costs of the rule for entities that submit only a few reports a year. Other comments expressed concern over the effective date and how to handle system outages; others included questions about the receipt date and FDA acknowledgments. Below is a summary of the comments received, grouped by subject matter.

B. Submitting Initial and Supplemental or Followup Reports (§ 803.12(a))

(Comment 1) Two comments stated that firms that only submit a few reports should be able to send reports on paper. One comment stated that the part 11 (21 CFR part 11) electronic documents and signature requirement is a burden for firms that never have needed to report electronically. The commenters objected to the expense of installing and validating the eSubmitter software. One suggested that PDF scans of documents be allowed.

(Response) The Agency disagrees with these comments as they apply to manufacturers and importers. Electronic reporting will improve the Agency's process for collecting and analyzing postmarket medical device adverse event information in a timely and efficient manner. If each manufacturer and importer that only had a “few reports” was exempt from the electronic reporting requirement, the cumulative effect would leave FDA with potentially thousands of reports to enter manually. Thus, the aggregate effect of exempting such manufacturers and importers would significantly undermine the

benefits of an electronic system of adverse event reporting. The burden and expense of adopting electronic reporting is minimal. The eSubmitter software has been designed and validated by FDA and is being made available to users for free. The user is expected to install and operate the software in accordance with the instructions provided by FDA. Section VI provides additional detail on the costs associated with this rule. For more information regarding the FDA's current thinking and enforcement policy relating to electronic records requirements under part 11, see the Agency guidance document entitled “Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application” available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf5667fml.pdf>.

The Agency has reassessed the proposal as it applies to user facilities, which are required to submit only device-related deaths directly to FDA. FDA estimates that user facilities comprise approximately two-thirds of all entities subject to reporting requirements under part 803, but provide only 3 percent of mandatory reports. In light of the anticipated cost for all user facilities to implement electronic reporting, the relatively small number of reports filed and correspondingly small savings to the Agency from mandating electronic reporting by user facilities, FDA is not mandating electronic reporting for user facilities at this time. Such facilities will be allowed to file paper reports, although—as is the case now—they can voluntarily choose to use electronic reporting, and the Agency encourages them to adopt electronic filing.

(Comment 2) One comment stated that FDA should allow the manufacturer to submit a supplemental report before issuing a request for additional information.

(Response) The Agency disagrees with this comment. We issue a request for additional information when our analysis of available submissions from the manufacturer identifies a need for additional information. Processing of paper submissions involves backlogs and delays in entry of the information into the database. One advantage of electronic reporting is that supplemental reports will be quickly available for review. Ready access to supplemental report information may reduce the need for additional information requests.

C. Establishing and Maintaining MDR Records (§ 803.18)

(Comment 3) Two comments considered the required .xml format to be a problem. One said that FDA field investigators may not be able to accurately interpret the electronic MDR .xml files to determine if the MDR is adequate or if the MDR was submitted on time. The second said that the .xml format is difficult for people to read and FDA should provide guidance on creating acceptable MDR documents from submitted .xml files that can be used by FDA field investigators.

(Response) The Agency does not believe that the .xml format is inherently problematic, but the Agency has developed guidance to assist entities with eMDR issues and a notice of availability for this guidance appears elsewhere in this issue of the **Federal Register**. Reporting entities that develop applications using the HL7 ICSR standard are encouraged to develop functions to save or print the reports in a human readable format. The reporting entities will need to validate that the human readable format is an accurate representation of what was submitted.

D. Copies Kept in MDR Files of All Reports Submitted (§ 803.18(b)(1)(ii))

(Comment 4) One comment stated that the reference to paper is no longer necessary and should be deleted from the phrase “(whether paper or electronic)”.

(Response) The Agency disagrees because paper copies will still be used in certain circumstances. A reporting entity that files paper copies of MDR reports with FDA or other entities could choose to maintain a paper copy of the report in its MDR event files. A reporting entity that uses HL7 to file an electronic MDR can maintain either an electronic or paper copy of the MDR in its MDR files, but the HL7 application needs to have validated that any paper copy produced is an accurate representation of the electronic copy filed with FDA. A reporting entity that uses eSubmitter to file an electronic MDR can use a feature of eSubmitter to produce a paper copy of the MDR when it is needed and validation of the copy is not required. If a reporting entity is granted an exemption from electronic reporting and the MDR report is sent on paper, it is likely that the entity would maintain a paper copy of the report sent to FDA in the MDR event file.

E. Copies of All Electronic Acknowledgments (§ 803.18(b)(1)(iii))

(Comment 5) One comment stated that FDA is requiring manufacturers to

keep all three of the acknowledgments sent by FDA even though the MDR filing is not considered successful until the firm receives Acknowledgment 3 and it shows the submission did not fail. The commenter recommended changing the regulation to eliminate retaining all of the acknowledgments sent by FDA. The commenter suggested requiring manufacturers to retain only proof of the MDR being filed and not the acknowledgments sent by FDA, or only the final acknowledgment. According to the commenter, Acknowledgments 1 and 2 should be invisible to the manufacturers; a single acknowledgment to the manufacturer should suffice.

(Comment 6) One comment stated that the three acknowledgments sent by FDA are cumbersome and difficult to link together. The commenter suggested consolidating the acknowledgments.

(Response) The Agency disagrees. Each acknowledgment sent by FDA indicates the stage of processing that has been reached (FDA ESG received, CDRH received, CDRH loaded into database) and whether it has been successfully processed. The date the report reaches the FDA ESG (marked by Acknowledgment 1) is considered the date received only if the report is successfully loaded into the CDRH database (marked by Acknowledgment 3), and Acknowledgment 2 links the information from the other two acknowledgments. If the submission has data errors, it will not be loaded into the CDRH database, and the submission must be corrected and resubmitted. All three acknowledgments are needed to trace the reference numbers from the initial receipt at FDA's ESG to the successful loading of the submission into the CDRH database, and the comments do not indicate why retention of them would be particularly burdensome. Until a report has been successfully processed, the reporting entity has not satisfied the requirement for submission of the MDR report. Moreover, in the event there is a question or problem relating to a submission, the receipt or lack of receipt of each of the three acknowledgments will assist the reporter and CDRH in determining the status of the report and will allow a reporter to identify and address any problems. For instance, failure to receive Acknowledgment 1 would indicate that it was not successfully received by the FDA ESG; if there was only one consolidated acknowledgment, the reporter would not know which aspect of the transmission failed and would not identify the problem as easily.

(Comment 7) One comment suggested that the Agency add a question, “When can I expect to receive my three acknowledgment notices?” to the eMDR guidance document.

(Response) FDA has added the question “How do I know FDA received my Electronic Submission and it was successfully processed?” to the preamble (see section II, Overview of the Final Rule). Moreover, FDA has addressed this question in the final guidance document for eMDR.

(Comment 8) One comment asked what to do if the firm does not receive all of the acknowledgments.

(Response) FDA considers a submission to be complete when all three acknowledgments have issued, indicating that the report has been successfully loaded in the CDRH adverse event database. If you do not receive Acknowledgments 1 or 2, and the ESG Web site does not indicate that there are problems with the operation of the FDA ESG, you should contact the FDA ESG staff. If you do not receive Acknowledgment 3, and the electronic MDR (eMDR) status page does not indicate that there are problems with the operation of eMDR, you should send an email message to: eMDR@fda.hhs.gov. If Acknowledgment 3 states that your report failed to load, the letter will identify errors in your submission. You will need to correct the errors and resubmit the report, at which time you will receive another set of three acknowledgments.

FDA considers the receipt date for electronic adverse event report submissions to be the date the submission arrived at the FDA ESG, but only if the submission is successfully loaded in the CDRH database. If a report is resubmitted and the resubmission is successfully loaded, the receipt date will be the date that the resubmission arrived at the FDA ESG.

Criteria that could cause a submission to fail include, but are not limited to, failure to provide data in a required field, failure to use the appropriate format for a field (e.g. an incorrect date format), data that exceeds the number of characters allowed for a field, or an invalid Report Number (e.g. the year and sequence number reversed or a sequence number reused). If there is a problem with the ESG or eMDR, FDA will post information concerning the problem on the appropriate Web site. You would not need to contact FDA, but should keep records of your attempt to submit MDR reports. FDA will use the Web site to advise when to expect operations to return to normal so that resubmission can be made. If you have questions during that time, send an

email in accordance with the instructions at the eMDR Web site: <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm> or the ESG Web site: <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>.

F. Manufacturer Reporting Requirements (§ 803.50(a))

(Comment 9) Two commenters asked for clarification about what date and time FDA will accept as timely submission. One comment stated that the Agency should clarify when electronic MDRs are considered to be reported, upon receipt into the FDA ESG or upon notification by CDRH that the report has been successfully loaded into CDRH's adverse event database. The second comment asked the Agency to specify what time zone to use to determine the 30-day requirement and recommended that the time zone of the submitter should be used.

(Response) For paper reports, FDA considers the postmark date or the date shipped by a delivery service to be the date the event was reported. For electronic reports, the date the eMDR submission is received at the FDA ESG is identified as the receipt date (i.e. the date the event was reported) for the MDR report, if the report is successfully loaded in the CDRH database. If a report cannot be loaded by CDRH, it is rejected and must be corrected and resubmitted. FDA does not have the benefit of the report information until the report is successfully loaded.

The time zone should not be a concern for timely reporting under MDR. The FDA ESG acknowledgment letter (Acknowledgment 1) displays both the date and time according to the Eastern Standard Time (EST)/Eastern Daylight Time (EDT) zone; however, MDR considers only the date for the purposes of calculating timely reporting. If the report is successfully loaded, this processing should take no more than an hour. Although Acknowledgment 1 displays EST/EDT, for purposes of timeliness FDA will consider the local time of the submitter, just as a postmark date is used for mailed paper reports. See section III.Q for further information.

G. Report Date (§ 803.52(b)(4))

(Comment 10) One comment stated that to avoid confusion the Agency should revise § 803.52(b)(4) back to the language in the current MDR regulation, to state: "Date of the report by the initial reporter." According to the comment, that date, plus the date required under § 803.52(e)(4), "Date received by you" would permit a clear tracking of

compliance with the regulation's reporting timeframes.

(Response) FDA disagrees. The date received by you is the date that you become aware of the event, which is also reported elsewhere on Form FDA 3500A. We are asking for the "Date of this report" to provide the reporting entity with a means of documenting the date that the MDR is submitted to FDA. This change will make the information requested for device reports consistent with the information recorded by other Centers for products that are reported using the Form FDA 3500A.

H. Product Code and Common Device Name (§ 803.52(c)(2))

(Comment 11) One comment stated that there is no need for both the product code and the common device name. It was suggested that the "and" be replaced with an "or."

(Response) FDA disagrees. The product code does not always match directly with a single common device name. Using both the product code and common device name provides FDA more specific information concerning the device that is the subject of the adverse event report. The product code is information that was initially required for the baseline report, and is needed as part of the information for Form FDA 3500A because the baseline report requirement has been removed from the MDR regulation. (See section I).

I. Name and Address of the Reprocessor (Revised § 803.52(c)(8) and (c)(9))

(Comment 12) One comment stated that the Agency should revise or clarify that these fields [Block D8 and 9 on Form FDA 3500A] apply only to reprocessors. An original equipment manufacturer that receives information about a reprocessed device for which the name and address of the reprocessor is known will send that information to the reprocessor because the reprocessor is the manufacturer for the purposes of MDR reporting.

(Response) FDA disagrees. Form FDA 3500A was modified as a result of the MDUFMA mandate. The form and instructions specify that under Block D. Suspect Medical Device, field 8 should be answered to identify single use devices that are reprocessed, and if the answer to field 8 is yes, field 9 should be completed to identify the name and address of the reprocessor. With this final rule we are revising the regulation to reflect the questions that are part of Form FDA 3500A. Because a reprocessor of a single use device is considered a manufacturer, the name and address of the reprocessor will also

appear in Section G of the report form. Although this may result in duplication of information, changes to the form are beyond the scope of this regulation.

J. Premarket Approval Application (PMA)/Section 510(k) Number and Combination Product Status (§ 803.52(e)(5))

(Comment 13) One comment suggested deleting § 803.52(e)(5) because PMA/510(k) number and combination product status have never been part of the MDR reporting provisions. This information was part of the old baseline reports, but the burden for submitting this information for each MDR is significantly more onerous than submitting this information in one baseline report on the device model. Many manufacturers would have to add systems to connect the complaint/MDR systems with their submissions systems, significantly increasing the economic burden of the rule and adversely affecting the ability to comply with electronic MDR requirements timeframes.

(Response) FDA disagrees. The comment did not provide any support for considering this to be a significant burden, and FDA believes there is good reason for making this change. FDA added these elements to Form FDA 3500A in 2005 because the Agency was removing the baseline reporting requirement. The change in the regulation codifies the previous changes to the form.

K. New, Changed, or Corrected Information (§ 803.56(c))

(Comment 14) Several comments stated that firms should be able to send a new complete report when submitting supplemental reports. One comment stated that submissions of additional information should be submitted on paper if the initial report was not submitted electronically.

(Response) FDA disagrees. The requirement to report only new, changed, or corrected information is consistent with the current regulation and the requirements and limitations of the CDRH database used for MDRs. FDA is developing specifications for the new database, however, and may be able to address this suggestion in the future. The use of electronic reporting for supplemental reports will provide FDA with more timely access to new, changed, or corrected information to facilitate the evaluation of adverse events that are reported.

L. Paper Responses to Requests for Additional Information

(Comment 15) One comment asked if responses to requests for additional information could be submitted on paper.

(Response) Yes, a response to a written request for additional information under § 803.15 can be submitted on paper. However, the use of electronic reporting for responses to requests for additional information provides FDA with more timely access to the information to facilitate the evaluation of adverse events that are reported. An additional information response should include the initial Report Number, indicate that the type of followup is a "Response to FDA Request," and provide the additional information requested as Additional Manufacturer Narrative. Any discrete data elements should also be reported as additional manufacturer narrative. You can also include a copy of the letter request sent by FDA as an attachment to the response.

M. Analysis of Impact

(Comment 16) One comment stated that our estimate of 10 hours for the burden to rewrite standard operating procedures (SOPs) and train personnel is too low. In its discussion, the commenter stated that it would take at least 40 hours to align a manufacturer's complaint handling systems to work compatibly with FDA's eSubmitter software.

(Response) The comment referred to our burden estimate for setting up systems for submission, which we estimated would require 8 to 16 hours. Our estimate was derived based on firms that maintained their MDR records in paper form. Companies with electronic complaint handling systems that do not intend to use HL7 ICSR could require approximately 40 hours to set up eSubmitter. We have amended our analysis of the economic impact of this rule to reflect the burden on such companies (see section VI).

N. Common Errors

(Comment 17) One comment suggested that the Agency add to the draft guidance a section on common errors that prevent a report from getting through the gateway or from being loaded successfully into the CDRH database.

(Response) FDA agrees with this suggestion. Examples of common errors include: Failure to provide data in a required field, failure to use the appropriate format for a field (e.g. an incorrect date format), data that exceeds

the number of characters allowed for a field, or use of an invalid Report Number. FDA has identified additional errors in a guidance document on reporting under eMDR requirements <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm175805.htm>.

O. Effective Date

(Comment 18) Three comments stated that 1 year is not enough time for firms to comply with the requirement to submit all MDRs electronically. One commenter stated that large firms need adequate time to design and implement the large volume option. Another said that the activities required for manufacturers to be able to submit eMDRs are considerable, particularly for companies with large numbers of filings. According to the commenter, software code of internal complaint tracking systems will need to be significantly redesigned, developed, and validated to send eMDRs, provide attachments, and track and retain FDA acknowledgments. Ensuring that implementation of the electronic reporting system adheres to the firm's data encryption, network, electronic message storage (for acknowledgments), and application security policies and architecture will require significant analysis and may require major reworking of existing network and server architecture as well as security and electronic record retention policies. Moreover, successful readiness to submit electronically is also dependent upon FDA capacity. The firm recommended that FDA make the final rule effective 2 years after the publication of the final rule in the **Federal Register**.

(Response) FDA generally agrees with these comments. We have extended the time to 18 months, which should be enough time for the reporting entities to implement electronic reporting. A reporting entity that intends to use the HL7 software option, but is unable to develop and implement an HL7 application within 18 months of the publication of the final rule, can use eSubmitter until the entity is ready to use the HL7 application. Moreover, in special cases a firm could seek a delay in adopting electronic reporting under § 803.19.

A CDRH memorandum dated May 8, 2008, provided notice that CDRH was ready to accept electronic submissions for MDR reports of individual adverse events. The memorandum can be found in the part 11 docket Docket No. FDA-1992-S-0039-0054 (formerly Docket No. 92S-0251), available at <http://www.regulations.gov>. See also <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR-ElectronicMedicalDeviceReporting/default.htm>. Voluntary use of electronic reporting has been available to industry since that time and a number of manufacturers have already adopted electronic reporting.

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR-ElectronicMedicalDeviceReporting/default.htm. Voluntary use of electronic reporting has been available to industry since that time and a number of manufacturers have already adopted electronic reporting.

P. General Comment Concerning Numeric Data Fields

(Comment 19) One comment indicated that the software for completing data fields A2 and A4 (patient age and weight) of the Form FDA 3500A only accepts numeric entries. Without numeric information for these fields, the report cannot be submitted. The commenter suggested providing a mechanism to allow "no information" entry in fields A2 and A4.

(Response) FDA recognizes that some fields that are numeric do not allow for a "no information" response, but we cannot change this feature in eSubmitter. If a reporting entity using eSubmitter does not have a numeric value to enter in an optional field such as A2 or A4, and leaves the field blank, the report can be accepted by CDRH. The HL7 ICSR standard provides for several values for indicating "no information": ASKU (asked but unavailable), NI (no information), and NA (not applicable). Reporters developing applications using the HL7 standard can use these values.

Q. Receipt Date

(Comment 20) Three comments stated that the date of the first acknowledgment confirming that the submission was received by the FDA ESG should be considered the date received. The comments asked FDA to confirm that this is the date the Agency will use for regulatory purposes. One comment added the suggestion that the Agency combine the acknowledgments or provide them in .xml format and link the acknowledgments.

(Response) FDA agrees with the suggestion to clarify when the report is considered received. FDA considers the receipt date for electronic adverse event report submissions to be the date the submission arrived at the FDA ESG, if the submission is ultimately loaded successfully. If the submission cannot be loaded successfully, Acknowledgment 3 sent to the reporting entity will identify the errors. The reporter must correct the errors and resubmit the report. If a report is resubmitted and the resubmission is successfully loaded, the receipt date will be the date that the resubmission

arrived at the FDA ESG. Although we consider Acknowledgment 1 to be the date received for a submission, if a report is subsequently rejected due to errors and must be resubmitted, the date of receipt will be the date the FDA ESG receives the resubmission (and a new Acknowledgment 1 is generated). The reporting entity can document its initial effort to submit the report with the information from the first submission but if the initial submission failed we would not consider the report received until it has been successfully loaded into the CDRH adverse event database. See section III.F for further information.

R. Software Changes

(Comment 21) Three comments questioned FDA's policy and provisions for software change control and adequate notice of change. One suggested that FDA establish a clear policy for managing and communicating software changes and scheduled maintenance and noted that high volume reporters would need at least 12 months to implement software changes. Another asked FDA to clarify how we will communicate changes to software, data fields, and code lists.

(Response) FDA is committed to providing industry with adequate notice of any specification changes and, when possible, will ensure previous versions of such specifications can still be utilized to submit adverse events electronically. We will utilize our Web sites for MDR, eMDR, and FDA ESG as well as **Federal Register** documents to provide sufficient advance notification of changes to all stakeholders. We will work with stakeholders on implementation of the changes and expect to support previous specifications long enough to ensure that HL7 and eSubmitter users are able to make the necessary changes. The FDA ESG Web site provides notification of scheduled maintenance and a status history that documents unscheduled down time for the FDA ESG.

S. System Outages

(Comment 22) Four comments stated that FDA has not adequately addressed what firms should do when there are system outages and noted there are no provisions for compliance when electronic systems "go down." Several comments said that FDA should accept paper reports when there is a system outage. One comment said that the Agency should explicitly provide instruction regarding what reporters need to do when the FDA ESG is down. In that event, the comment indicated that manufacturers should receive a

comparable extension of time to file their reports.

FDA has suggested firms should document attempts at timely filing in Block H10 of the MDR form if the manufacturer's electronic systems are down. One comment indicated that this expectation should be explicitly set forth in the regulation. Doing so would put all firms on an even playing field and clarify what must be documented to demonstrate MDR compliance to FDA investigators.

(Response) FDA agrees that firms need to be advised how to document problems with timely filing. If either the ESG or a firm's electronic system experiences an outage affecting timely reporting, the reason for the late submission can be documented by the manufacturer, importer, or user facility in Block H10. FDA is not adding this to the rule because firms are not required to submit this information.

The FDA ESG Web site provides notification of planned maintenance and maintains a status history that documents times that the FDA ESG was not operating. Typically, an ESG system outage has not lasted more than 24 hours and should not require an extension of time. If a reporting entity is unable to submit a report on time due to an ESG outage, it should document its attempts at timely filing in Block H10 for the affected reports and submit reports electronically as soon as the ESG is operational.

A reporting entity using an HL7 reporting option should plan for a backup method of reporting for an outage affecting its own system. If a reporting entity experiences an outage within its own system that will affect timely reporting, it should contact FDA at the eMDR email address: eMDR@fda.hhs.gov. The email should provide FDA with information on the problem, the number of reports affected, and an estimate of how long it will take to resolve. We will respond concerning alternatives for submission of the adverse event reports. A description of the problem with the electronic submission should be documented in Block H10 for the affected reports before they are submitted.

IV. 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.

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, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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). OMB has determined that this final rule is a significant regulatory action under the Executive Order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the eSubmitter program for electronic submission of reports does not impose significant costs on small entities, 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 \$141 million, using the most current (2012) 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.

The principal benefit of this final rule will be the public health benefits associated with more rapid processing and analysis of the initial individual MDRs currently submitted by manufacturers and importers to FDA on a paper Form FDA 3500A (about

190,000 in 2011). In addition, requiring electronic submission of MDRs is expected to reduce FDA's annual operating costs by \$1.9 million and generate annual industry savings of about \$9.2 million.

The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from \$38.4 million to \$42.8 million. Estimated annually recurring costs totaled \$3.0 million and included 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 rule, using a 7-percent discount rate over 10 years, would be from \$8.5 million to \$9.1 million; with a 3-percent discount rate, the annualized cost would be \$7.5 million to \$8.0 million.

A. Need for Regulation

The purpose of this final rule is to require the submission of MDRs in an electronic format the Agency can process, review, and archive. It will affect all medical device manufacturers and importers.

The final rule is part of a greater Agency initiative to adopt electronic technologies to improve the quality of our operations and to use our resources more efficiently. The rule will reduce FDA's current costs associated with processing MDRs that are currently received on the paper Form FDA 3500A. By receiving MDRs electronically, FDA should be able to access the adverse event information more quickly and at a lower cost with anticipated reduced data entry errors by eliminating the step of having manufacturers prepare and submit paper forms.

After considering various alternatives, FDA determined that user facilities may continue to submit MDRs in paper form because their reports account for only about 3 percent of reports annually. A regulation is necessary for reports from manufacturers and importers because the Agency receives around 190,000 paper reports from such entities and it would be costly for the Agency to maintain the capacity to continue to convert paper Form FDA 3500A MDRs to electronic MDR records until all manufacturers and importers voluntarily adopted the electronic submission format, possibly years in the future. Some reporters might never adopt electronic reporting of their own volition.

B. Benefits

The most important benefit of this final rule will be to the public health

because the rule will enable the Agency to have quicker access to the medical device adverse event reports information and thus more quickly identify and act on any medical device problems. In 2011, FDA received approximately 201,000 initial MDRs from all sources on the paper Form FDA 3500A that needed to be processed and manually 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 Form FDA 3500A is available for analysis in the Manufacturer and User Facility Device Experience (MAUDE) database. With a standardized electronic format, the majority of medical device reports will be available for analysis within a day or two after submission to the FDA ESG. With a significant reduction in the time needed for MDRs to be included in the MAUDE database, analysis and action, including feedback to manufacturers and consumers, can be initiated sooner—with a corresponding benefit to public health.

The public health benefits will be supplemented with operating cost reductions within FDA. Assuming the number of MDRs remains fairly constant over time, electronic reporting will save the Agency about one-half of the cost of our data entry contract, which equals a savings of \$1.9 million annually.

C. Costs

There are about 20,100 medical device manufacturers and importers identified in FDA's medical device registration database that will be covered by the rule.

The incremental cost to each affected entity will vary by the size, type, and corporate structure of the firm, as well as by its existing electronic submission capability. The total costs associated with this final rule will include one-time setup costs and annual operating costs.

1. One-Time Costs

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

- Rewriting SOPs and training the appropriate personnel,
 - Installing and validating either:
 - The installation of the eSubmitter 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 subject to the electronic reporting requirement will need to ensure that their SOPs include

the electronic submission requirement. We estimate that it will require about 10 hours to make the modifications and train the appropriate people on the new procedures. The estimated one-time incremental cost for updating SOPs, assuming an average wage rate of \$63 per hour,² is about \$12.7 million (20,100 medical device manufacturers and importers × 10 hours × \$63/hour).

b. Setting up systems for submission. MDRs will be submitted through the FDA ESG using one of two methods: The eSubmitter software or the HL7 ICSR. Because most entities are small and submit few if any MDRs annually, we assume they will use the eSubmitter software, which allows for the submission of one MDR at a time. To comply using this submission method, manufacturers and importers will need high-speed Internet connections³ and will 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 staff will be able to install and validate the installation themselves. Smaller manufacturers and importers will probably choose to hire an outside contractor for the installation and the validation of the installation.

FDA does 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, FDA assumes that it will take 8 to 16 hours to install and validate the installation of the eSubmitter software (and to install, if necessary, Java Runtime Edition software and Java security policy files for their Internet browser) for manufacturers and importers who maintain paper records. FDA assumes it could take about 40 hours for manufacturers and importers who maintain electronic records (and thus need extra time to ensure that their systems can communicate with FDA ESG). These time totals also include 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. FDA also assumes that

² \$63 per hour wage is based on U.S. Bureau of Labor Statistics (BLS) Occupational Employment and Wages, May 2010, for Medical and Health Service Managers, Standard Occupational Classification 11–9111. Forty percent was added to the mean hourly wage of \$45.03 to account for benefits and the total was rounded to \$63.

³ While it is possible to submit reports with a slower, dial-up, connection, we believe most manufacturers and importers that do not have high-speed connections already would upgrade their Internet access because it is more efficient. The efficiencies of high speed Internet access could also benefit other parts of firms' business systems.

almost all medical device manufacturers and importers will use this method to submit MDRs. Using an average wage of \$52 for computer and mathematical occupations,⁴ we estimate the cost to install and use the software to be between \$25.2 million and \$29.4 million $[(8 \text{ hours} \times \$52 \text{ wage} \times 10,050 \text{ manufacturers and importers}) + (40 \text{ hours} \times \$52 \text{ wage} \times 10,050 \text{ manufacturers and importers})]$ to $[(16 \text{ hours} \times \$52 \text{ wage} \times 10,050 \text{ manufacturers and importers}) + (40 \text{ hours} \times \$52 \text{ wage} \times 10,050 \text{ manufacturers and importers})]$.

Entities that submit a large number of MDRs each year may choose to use the HL7 ICSR method to submit the reports. This method allows for the batch submission of multiple MDRs at faster transmission rates. The Agency does not know the threshold at which 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 medical device manufacturers submit 500 or more MDRs each year and about 85 submit close to 100 medical device reports per year. We assume that the actual number of entities that would

begin using the HL7 ICSR as a result of this rule would fall somewhere within this range (20 to 105). We also assume that only entities that have existing infrastructure to support HL7 ICSR transmissions would choose this method to submit MDRs. We estimate that it will take about 50 hours to set up their gateway to be compatible with the Agency's system. Using the wage \$52, the one-time cost for establishing HL7 ICSR submission capabilities will range between \$52 thousand and \$273 thousand $[(\$52 \times 50 \text{ hours}) \times 20 \text{ entities}]$ and $[(\$52 \times 50 \text{ hours}) \times 105 \text{ entities}]$.

c. Electronic certificates. All entities will 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 will incur a one-time cost to acquire the certificate and recurring costs to keep the certificate active as a result of this final 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 cost of \$40 for the first year, half of which would be setup costs. If all entities needed to acquire electronic certificates, the one-time initial costs of the certificates would be \$402,000 $(\$20 \text{ initial acquisition cost} \times 20,100 \text{ entities})$.

d. Summary of one-time costs. In addition to the costs we have estimated, manufacturers and importers affected by this final rule may have to hire outside experts to install and validate the software installation to comply with these requirements.

Table 1 summarizes the estimated one-time costs for this rule. The estimate of the total one-time costs for all affected entities ranges from \$38.4 million to \$42.8 million. Much of the cost involves acquiring the electronic certificate to submit any regulatory document to the FDA, including installation and validation of the eSubmitter software or establishment of HL7 ICSR capabilities. For this analysis we assume all manufacturers and importers will incur these costs when in fact some already have electronic certificates and voluntarily submit MDRs electronically.

TABLE 1—SUMMARY OF ONE-TIME COSTS
[\$ million]

Industry	Modifying SOPs	Install and validate eSubmitter software		Establish HL7 ICSR capability		Acquiring e-Certificate ¹	Total	
		Low	High	Low	High		Low	High
One-time costs	12.7	25.2	29.4	0.05	0.3	0.4	38.4	42.8
Annualized at 3-percent over 10 years	4.5	5.0
Annualized at 7-percent over 10 years	5.5	6.1

¹ This refers to the \$20 initial cost to acquire the e-certificate; the rest of the cost of the certificate is captured in the calculation of annual costs.

2. Annual Costs

The annual costs of this final rule will include the costs of:

- Maintaining certificates and
- High-speed Internet access.

a. Maintaining electronic certificates. Manufacturers and importers will bear the cost of maintaining 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 will also have to ensure that 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 will 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 and importers need to acquire electronic certificates, the annual cost would be \$0.6 million $(\$30 \text{ acquisition certificate renewal and acquisition cost} \times 20,100 \text{ entities})$.

b. High-speed Internet access. We have assumed that entities will also use high-speed Internet access to use either of the submission methods. A 2010 study of small businesses sponsored by the Small Business Administration (SBA) found that essentially all small firms had Internet access and about 80

percent had high-speed Internet access (Columbia Telecommunications Corp., 2010). The average cost of high speed access was about \$40 per month more than dial-up access. Because the average medical device manufacturer is very small and very small firms had somewhat lower access than the average, we estimate that by the time this final rule is in effect, about 75 percent of manufacturers and importers will 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 approximately \$2.4 million

⁴ BLS Occupational Employment and Wages, May 2010 by occupation, for all industries (<http://www.bls.gov>). Wage (\$52) includes mean hourly wage of \$37.13 for Standard Occupational

Classification 15-0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits and rounded to \$52 for ease of calculations. (FDA has verified the Web site

address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

(($\$40 \times 12$ months) $\times 0.25 \times 20,100$ manufacturers and importers).

c. Summary of annual costs. The annual costs of the rule are \$3 million (\$0.6 million for electronic certificates + \$2.4 million for internet access). As with the one-time costs, only entities not already making electronic regulatory document submissions of any kind to the Agency when this rule is published will incur these costs. There will be no change in the actual time required to research and prepare the MDRs, nor will there be any additional reporting requirements as a result of this final rule. Manufacturers and importers that maintain Form FDA 3500A records in paper format for their internal MDR files can still do so under this final rule.

d. Cost savings. FDA estimates an industry savings of about \$9.2 million annually because electronic submission should reduce the time it takes to submit documents and reduce postage or delivery expenditures. The time savings estimate was derived using the estimated savings (i.e., from reduced burdens) reported in section VII. Device manufacturers and importers are expected to save a weighted average of 0.89 hours per submission. Savings from reduced postage costs will be around \$0.4 million. FDA assumed that without this rule the Agency would continue to receive about 190,000 submissions in paper format.⁵ FDA calculated the total savings as 190,000 submissions \times 0.89 hour savings \times \$52 wage cost per hour + .8 \times [(1,630 firms \times 12 months \times (\$5 flat rate priority mail + \$20 flat rate express mail))].⁶

D. Regulatory Alternatives to the Final Rule

The Agency identified and assessed two additional regulatory alternatives to this final rule. The first of these alternatives would allow manufacturers and importers to voluntarily submit MDRs electronically. This regulatory alternative would allow firms to choose

paper or electronic submissions, but would require any electronic submissions to use either the eSubmitter or the HL7 ICSR. This alternative would reduce the one-time set costs (see table 1) for firms choosing not to make electronic submissions; those firms would also fail to realize corresponding savings. For many firms, the expected private costs of adopting electronic submissions will exceed expected private benefits due to having higher discount rates, higher costs than the averages presented here, or shorter planning horizons than the 10 years used in this analysis; FDA therefore expects that under this alternative a number of medical device firms would resist changing their procedures for a long period of time, perhaps indefinitely. If a substantial number failed to voluntarily adopt electronic submission of MDRs, FDA would not obtain the benefits of standardized formats and quicker access to medical device adverse event data. The Agency would also have to maintain significant capacity for accepting and processing written MDRs. A voluntary system, therefore, would fail to achieve the public health benefits and efficiency goals of the final rule.

The second regulatory alternative would allow small entities more time to comply with the electronic submission requirements. This alternative would allow small entities to delay compliance. Under this alternative, FDA would not achieve meaningful data entry savings from requiring electronic submissions or all the benefits of quicker access to these reports until the small entity compliance date. Because so many device companies are small entities, and in many cases their private costs will exceed their private benefits, small entities would likely postpone compliance, which would significantly postpone the benefits the rule is intended to confer. As shown in the

following section, the estimated incremental costs per small entity from the final rule are small, so the cost reduction per small entity from delayed compliance would also be small. Moreover, postponing compliance would not reduce the future setup costs once the later compliance date is reached. In other words, postponing compliance would simply postpone the costs and benefits with no change in their amounts.

E. Regulatory Flexibility Analysis

SBA defines a small medical device manufacturer as having fewer than 500 employees (NAICS 325413, 334510, 334517, 339112, 339113, 339114, and 339115). Over 90 percent of registered device firms affected by this final rule are considered small entities under this definition. While this final rule will now require many MDR 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 paper Form FDA 3500A. The average costs for these manufacturers and importers are listed in table 2. The average total annualized cost per small entity, assuming a 7-percent discount rate over 10 years, would range from \$590 to \$720 (\$575 to \$680 at a 3-percent discount rate).

Because the costs per affected entity are low compared to revenues, FDA finds that although this final rule will affect a substantial number of small entities, it will not have a significant economic impact on those entities. For example, for a facility in NAICS 339114, dental equipment and supplies, which have the lowest value of shipments of all affected industries, \$4.4 million, \$721 in annualized costs represents about 0.02 percent of revenues. We therefore certify that the final rule will not have a significant economic impact on a substantial number of small entities.

TABLE 2—INCREMENTAL COMPLIANCE COSTS PER SMALL ENTITY

	One-time costs		Annually recurring	Total annualized	
	Low	High		Low	High
Rewriting SOPs	123	613
Software Installation and Validation of Installation	411	822
Acquiring Electronic Certificate	40	
Maintaining Submission Capabilities	30
Upgrade Internet Access	480

⁵ The estimated 190,000 submissions from 1,630 firms are based on the number of submissions for 2011.

⁶ This estimate differs from the paperwork estimates in section VII because it measures the incremental change from current practice rather than the time to comply with specific requirements. Postage was calculated using flat rate charges by the

U.S. Postal Service and assuming that 80 percent of the firms submitting paper MDRs in a given year would submit one express package and one priority mail package per month.

TABLE 2—INCREMENTAL COMPLIANCE COSTS PER SMALL ENTITY—Continued

	One-time costs		Annually recurring	Total annualized	
	Low	High		Low	High
7-Percent Discount Rate	590	720
3-Percent Discount Rate	575	680

VII. How does this rule comply with the PRA?

This final rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs 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.

Title: Medical Device Reporting: Electronic Submission Requirements.

Description: In accordance with this final rule, medical device manufacturers, importers, and user facilities will be required to submit electronic MDRs to FDA and to maintain records, and may also seek exemption from these requirements. FDA is also amending §§ 803.32, 803.42, and 803.52 by making minor revisions to reflect prior modifications to Form FDA 3500A and its instructions. Manufacturers, importers, and user facilities are currently submitting paper MDRs on Form FDA 3500A, approved under OMB control number 0910–0291. User facilities are currently submitting paper annual reports on Form FDA 3419, approved under OMB control number 0910–0437.

Section 519(a)(1) of the FD&C Act 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 may have caused or contributed to a death or serious injury, or 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 FD&C Act requires that “[w]henver 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 FD&C Act requires that “[w]henver 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 FD&C Act. FDA is requesting approval for the information collection requirements contained in part 803 as revised by this final rule.

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).

FDA received 35 comments on the 2009 proposed rule (74 FR 42203). Thirteen comments were related to the collections of information. All comments are discussed in detail in section III (see comments 1 through 6, 9 through 14, and 16.)

To calculate the annual reporting burden for table 3, the number of reporting entities that had filed MDRs during 3 years (January 1, 2006, through December 31, 2008) was identified along with the number of MDR reports filed during that time period. The rate of

increase in reports and supplements filed was determined and projected for the next 3 years. The projected total annual responses were calculated by multiplying the projected number of respondents by the annual frequency per response for the reports and supplements, resulting in the estimated total that would be filed by each entity.⁷ The figures displayed in table 3 of the 2009 proposed rule were based on MDRs processed during the year July 1, 2005, to June 30, 2006, but for this final rule FDA has used data for the years 2006 to 2008. One exception is the counts under exemption reporting (§ 803.19), which reflect the number of firms that currently have an exemption and have submitted quarterly reports in 2009. The annual burden for reporting calculated in table 3 is 37,709 hours.

To calculate the cost figures in table 3, we based our estimates on a count of all manufacturers, importers, and user facilities that filed MDRs during the period 2006 to 2008. The estimate of capital costs included:

- Development of procedures for handling adverse events and reporting MDRs,
- Installation of eSubmitter and/or installation and validation of H7, and
- Acquiring an electronic certificate.

The maximum and minimum estimates for installation of eSubmitter and HL7 were averaged in the calculations for capital costs. The estimate of annual operating and maintenance costs included:

- Renewal of electronic certificate and
- Maintenance of high-speed Internet access.

The total annual estimated burden imposed by this collection of information from tables 3 and 4 is 46,445 hours annually. The approved MDR reporting and recordkeeping burden for paper submissions is 391,526 hours, as approved under OMB control number 0910–0437 (expires August 31, 2015). Based on 46,445 hours as the reporting and recordkeeping burden for electronic submissions, there is a burden decrease of 345,081 hours. An

⁷ In 2012, the actual number of MDR reports submitted was 712,000, higher than had been estimated.

explanation for the burden decrease is provided in the following paragraphs:

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs (mil)	Total annual operating and maintenance costs (mil)
803.19	56	4	224	1	224
803.30 and 803.32	520	7	3,640	0.35	1,274	\$5.9	\$0.9
803.33	3419	520	1	520	1	520
803.40 and 803.42	60	25	1,500	0.35	525	1.5	0.1
803.50 and 803.52	1,240	204	252,960	0.10	25,296	6.6	0.5
803.56	1,050	94	98,700	0.10	9,870
Total	37,709	14.0	1.5

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
803.17	1,820	1	1,820	3.3	6,006
803.18(a) through (d)	1,820	1	1,820	1.5	2,730
Total	8,736

A. Reporting Requirements

The number of respondents for each applicable Code of Federal Regulations (CFR) reporting requirement in table 3 was identified from the MDRs reported to FDA's internal databases during the period January 1, 2006, through December 31, 2008. The annual frequency per response and total annual responses shown were based on the number of MDRs reported during the same period (January 1, 2006, through December 31, 2008) with a calculated increase for the next 3 years. FDA estimates that electronic submission will decrease the burden associated with §§ 803.19, 803.30, 803.32, 803.40, 803.42, 803.50, 803.52, and 803.56.

B. Recordkeeping Requirements

The number of respondents for each CFR section in table 4 was identified from the MDRs reported to FDA's internal databases during the period January 1, 2006, through December 31, 2008. The Agency believes that the majority of manufacturers, user facilities, and importers has already established written procedures and MDR files to document complaints and information to meet the MDR requirements as part of their internal quality control system, but will need to modify their practices to address the electronic reporting process.

C. Changes From the Proposed Rule

The total burden hours for the proposed rule were 15,200 and total burden hours for the final rule are 37,709. This is an increase of 22,509. The proposed rule calculations were based on MDRs processed during the year July 1, 2005, to June 30, 2006. The final rule calculations were based on MDR data for the period January 1, 2006, through December 31, 2008. The hours per response were adjusted to simplify calculations. These changes resulted in an increase in burden between the proposed rule and the final rule. The following table 5 identifies the burden changes from the proposed rule to the final rule.

TABLE 5—CHANGES FROM THE PROPOSED RULE

21 CFR Section	Number of respondents		Number of responses per respondent		Average burden per response		Total burden hours	
	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final
803.19	55	56	4	4	1	1	220	224
803.30 and 803.32	411	520	2	7	0.33	0.35	271	1,274
803.33	411	520	1	1	1	1	411	520
803.40 and 803.42	44	60	20	25	0.33	0.35	290	525
803.50 and 803.52	1,304	1,240	58	204	.011	0.10	8,248	25,296
803.56	1,200	1,050	48	94	0.10	0.10	5,760	9,870
Total	15,272	37,709

The following table 6 summarizes FDA's burden estimates and how they will change due to electronic

submission. Table 7 summarizes our recordkeeping burden estimates and

how we believe they will change due to electronic submission.

TABLE 6—ESTIMATED REPORTING BURDEN PROGRAM CHANGE

21 CFR Section	Average burden per response under current paper submission process	Average burden per response as a result of electronic submission	Burden change reduction (hours)
803.19	3	1	2
803.30 and 803.32	1	0.35	0.65
803.33	1	1	(*)
803.40 and 803.42	1	0.35	0.65
803.50 and 803.52	1	0.10	0.9
803.56	1	0.10	.9

* No change.

As previously described, there are two reporting options. The first one is eSubmitter for low volume reporters, and the second one is HL7 ICSR for high volume reporters. FDA is basing its hours per response estimates on industry's voluntary use of the two systems since May 2008.

TABLE 7—ESTIMATED RECORDKEEPING BURDEN PROGRAM CHANGE

21 CFR Section	Average burden per recordkeeping under current paper submission process	Average burden per recordkeeping as a result of electronic submission	Burden change reduction (hours)
803.17	10.0	3.3	6.7
803.18(a) through (d)	1.5	1.5	(*)

* No change.

D. Total Annual Cost Burden

The conversion from paper to electronic submissions will result in a burden to reporting entities due to both capital costs (one-time setup costs) and annual operating and maintenance costs, as demonstrated in table 3 and discussed in section VI. The one-time capital costs include the cost to develop procedures for handling adverse events and reporting MDRs, installing the eSubmitter software and/or installing gateway to gateway submission capabilities (HL7), and acquiring electronic certificates; these costs have been estimated at \$14.0 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 has been estimated at \$1.5 million each year.

This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The revised Form FDA 3500A is approved under the PRA, under OMB control number 0910–0291. The collections of information in part 803 have been approved under OMB control number 0910–0437.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Does this final rule have federalism implications?

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. What is the effective date?

This final rule is effective August 14, 2015 (see **DATES** section). Reporting entities that are unable to comply with this date should request an exemption following the process described

elsewhere in this document and in the MDR regulation under § 803.19.

X. What references are on display?

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Census Bureau, 2007 Economic Census Industry Series: NAICS Code 62, Health Care and Social Assistance, (<http://www.census.gov>), April 1, 2011.
2. BLS Occupational Employment and Wages, May 2010 for Medical and Health Service Managers, Standard Occupational Classification, 11–19111, (<http://www.bls.gov>), April 1, 2011.
3. Columbia Telecommunications Corp., *The Impact of Broadband Speed and Price on Small Business*, SBA Office of Advocacy Contract Number SBAHQ–09–C–0050, (<http://archive.sba.gov/advo/research/rs373tot.pdf>), November 2010.

XI. Stayed CFR Text

FDA has many revisions for 21 CFR part 803; therefore, we are revising the entire part. At 73 FR 33692, published June 13, 2008, FDA amended the MDR regulation to remove § 803.55, which

established the requirement for baseline reports. Section 803.58, which is currently under indefinite stay (published at 61 FR 38346, July 23, 1996), includes in subsection (b)(1) a reference to the former § 803.55. For purposes of this rulemaking, FDA is temporarily lifting the stay of § 803.58 in order to remove the reference to § 803.55. Because FDA is only lifting the stay for this purpose, we are also reimposing the indefinite stay of § 803.58 in this final rule. FDA intends to consider the § 803.58 requirements for U.S.-designated agents in a separate rulemaking.

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:

§ 803.58 [Amended]

- 1. The stay of § 803.58 published at 61 FR 38346, July 23, 1996, is lifted.
- 2. Revise part 803 to read as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

- 803.1 What does this part cover?
- 803.3 How does FDA define the terms used in this part?
- 803.9 What information from the reports do we disclose to the public?
- 803.10 Generally, what are the reporting requirements that apply to me?
- 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?
- 803.12 How do I submit initial and supplemental or followup reports?
- 803.13 Do I need to submit reports in English?
- 803.15 How will I know if you require more information about my medical device report?
- 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?
- 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?
- 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?
- 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

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

- 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

- 803.22 What are the circumstances in which I am not required to file a report?

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

Subpart C—User Facility Reporting Requirements

- 803.30 If I am a user facility, what reporting requirements apply to me?
- 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?
- 803.33 If I am a user facility, what must I include when I submit an annual report?

Subpart D—Importer Reporting Requirements

- 803.40 If I am an importer, what reporting requirements apply to me?
- 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

Subpart E—Manufacturer Reporting Requirements

- 803.50 If I am a manufacturer, what reporting requirements apply to me?
- 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?
- 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?
- 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?
- 803.58 Foreign manufacturers.

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

Subpart A—General Provisions

§ 803.1 What does this part cover?

(a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical device distributor, you must

maintain records (files) of incidents, but you are not required to report these incidents.

(b) This part supplements and does not supersede other provisions of this chapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 803.3 How does FDA define the terms used in this part?

Some of the terms we use in this part are specific to medical device reporting and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section defines the following terms as used in this part:

(a) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(b) *Become aware* means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

(1) If you are a device user facility, you are considered to have “become aware” when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.

(2) If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with § 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate

to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within 30 days.

(c) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- (1) Failure,
- (2) Malfunction,
- (3) Improper or inadequate design,
- (4) Manufacture,
- (5) Labeling, or
- (6) User error.

(d) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.

(e) *Distributor* means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

(f) *Expected life of a device* means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified "end of life" (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.

(g) *FDA, we, us, or Agency* means the Food and Drug Administration.

(h) *Five-day report* means a medical device report that must be submitted by a manufacturer to us under § 803.53 within 5 work days.

(i) *Hospital* means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such

as medical, occupational, speech, physical), surgical, and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure, or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

(j) *Importer* means any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

(k) *Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.

(l) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified

person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

(m) *Manufacturer or importer report number*. This number uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts:

(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting number;

(2) The four-digit calendar year in which the report is submitted; and

(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567–2011–00001.)

(n) *MDR* means medical device report.

(o) *MDR reportable event (or reportable event)* means:

(1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or

(2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:

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

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

(p) *Medical personnel* means an individual who:

(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports; or

(4) Is a supervisor of these persons.

(q) *Nursing home* means:

(1) An independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.

(r) *Outpatient diagnostic facility* means:

(1) A distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients,

(ii) Does not assume ongoing responsibility for patient care, and

(iii) Provides its services for use by other medical personnel.

(2) Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

(s) *Outpatient treatment facility* means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or in a home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include the following: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any

other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(t) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(u) *Physician's office* means a facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include: Dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(v) *Remedial action* means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

(w) *Serious injury* means an injury or illness that:

(1) Is life-threatening,

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

(x) *User facility report number* means the number that uniquely identifies each report submitted by a user facility to manufacturers and to us. This number consists of the following three parts:

(1) The user facility's 10-digit Centers for Medicare and Medicaid Services (CMS) number (if the CMS number has

fewer than 10 digits, fill the remaining spaces with zeros);

(2) The four-digit calendar year in which the report is submitted; and

(3) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete user facility report number will appear as follows: 1234560000–2011–0001. If a user facility has more than one CMS number, it must select one that will be used for all of its MDR reports. If a user facility has no CMS number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–2011–0001). We will assign a number for future use and send that number to the user facility. This number is used in our record of the initial report, in subsequent reports, and in any correspondence with the user facility. If a facility has multiple sites, the primary site may submit reports for all sites and use one reporting number for all sites if the primary site provides the name, address, and CMS number for each respective site.)

(y) *Work day* means Monday through Friday, except Federal holidays.

(z) [Reserved]

§ 803.9 What information from the reports do we disclose to the public?

(a) We may disclose to the public any report, including any FDA record of a telephone report, submitted under this part. Our disclosures are governed by part 20 of this chapter.

(b) Before we disclose a report to the public, we will delete the following:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;

(2) Any personal, medical, and similar information, including the serial number of implanted devices, which would constitute an invasion of personal privacy under § 20.63 of this chapter. However, if a patient requests a report, we will disclose to that patient all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and

(3) Any names and other identifying information of a third party that voluntarily submitted an adverse event report.

(c) We may not disclose the identity of a device user facility that makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)), including the failure or refusal to furnish material or information required by section 519 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 360i));

(2) A communication to a manufacturer of a device that is the subject of a report required to be submitted by a user facility under § 803.30; or

(3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

§ 803.10 Generally, what are the reporting requirements that apply to me?

(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:

(1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths to us and to the manufacturer, if known, or

(ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.

(2) Submit annual reports (described in § 803.33) to us.

(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer or

(ii) Submit reports of device-related malfunctions to the manufacturer.

(2) [Reserved]

(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:

(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or

(ii) A reportable event for which we made a written request.

(3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

(a) If you are a manufacturer or importer, you must submit reports of

individual adverse events to FDA in an electronic format in accordance with § 803.12(a) and § 803.20, unless granted an exemption under § 803.19.

(b) Importer reports submitted to device manufacturers may be in paper format or an electronic format that includes all required data fields to ensure that the manufacturer has all required information.

(c) If you are a user facility, you must submit reports of individual adverse events in accordance with § 803.12(b) and § 803.20.

(d) Form FDA 3500A is available on the Internet at <http://www.fda.gov/medwatch/getforms.htm> or from Division of Small Manufacturers, International and Consumer Assistance, Office of Communication and Education, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993-0002, by email: DSMICA@fda.hhs.gov, FAX: 301-847-8149, or telephone: 800-638-2041.

§ 803.12 How do I submit initial and supplemental or followup reports?

(a) Manufacturers and importers must submit initial and supplemental or followup reports to FDA in an electronic format that FDA can process, review, and archive.

(b) User facilities that submit their reports and additional information to FDA electronically must use an electronic format that FDA can process, review, and archive. User facilities that submit their reports to FDA on paper must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002, using Form FDA 3500A. Each report must be identified (e.g., "User Facility Report" or "Annual Report").

(c) If you are confronted with a public health emergency, this can be brought to FDA's attention by contacting FDA's Office of Crisis Management, Emergency Operations Center by telephone, 24-hours a day, at 301-796-8240 or toll free at 866-300-4374, followed by the submission of an email to: emergency.operations@fda.hhs.gov.

Note: This action does not satisfy your obligation to report under part 803.

(d) 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 Form FDA 3500 and instructions to complete it at: <http://www.fda.gov/Safety/MedWatch/>

HowToReport/DownloadForms/default.htm.

§ 803.13 Do I need to submit reports in English?

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

§ 803.15 How will I know if you require more information about my medical device report?

(a) We will notify you in writing if we require additional information and will tell you what information we need. We will require additional information if we determine that protection of the public health requires additional or clarifying information for medical device reports submitted to us and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible to us.

(b) In any request under this section, we will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. If we verbally request additional information, we will confirm the request in writing.

§ 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?

No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

§ 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?

If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;

(2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.

(b) Documentation and recordkeeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to manufacturers and/or us;

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by us.

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

(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.

(b)(1) For purposes of this part, “MDR event files” are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:

(i) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decision making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part;

(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; and

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

(2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(c) If you are a user facility, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. If you are a manufacturer or importer, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this paragraph (c).

(d)(1) If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.

(2) You must retain copies of the required device incident records for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater. You must maintain copies of these records for this period even if you no longer distribute the device.

(3) You must maintain the device complaint files established under this section at your principal business establishment. If you are also a manufacturer, you may maintain the file at the same location as you maintain your complaint file under part 820 of this chapter. You must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

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

(a) We exempt the following persons from the adverse event reporting requirements in this part:

(1) A licensed practitioner who prescribes or administers devices intended for use in humans and manufactures or imports devices solely for use in diagnosing and treating

persons with whom the practitioner has a “physician-patient” relationship;

(2) An individual who manufactures devices intended for use in humans solely for this person’s use in research or teaching and not for sale. This includes any person who is subject to alternative reporting requirements under the investigational device exemption regulations (described in part 812 of this chapter), which require reporting of all adverse device effects; and

(3) Dental laboratories or optical laboratories.

(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. You must submit the request to us in writing at the following address: MDR Exemption Requests, Office of Surveillance and Biometrics, 10903 New Hampshire Ave., Bldg. 66, Rm. 3217, Silver Spring, MD 20993–0002. 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 an exemption from the requirement to submit reports to FDA in electronic format under § 803.12(a), your request should indicate for how long you will require this exemption.

(c) If you are a manufacturer, importer, or user facility, we may grant in writing an exemption or variance from, or alternative to, any or all of the reporting requirements in this part, and may change the frequency of reporting to quarterly, semiannually, annually or other appropriate time period. We may grant these modifications in response to your request, as described in paragraph (b) of this section, or at our discretion. When we grant modifications to the reporting requirements, we may impose other reporting requirements to ensure the protection of public health.

(d) We may revoke or modify in writing an exemption, variance, or alternative reporting requirement if we determine that revocation or modification is necessary to protect the public health.

(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.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

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

(a) *What form must I complete and submit?*

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

(2) To submit a mandatory report in written form, a user facility must use Form FDA 3500A.

(3) An electronic submission of a mandatory report from a user facility, importer, or manufacturer must contain the information from the applicable blocks of Form FDA 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.

(b) *To whom must I submit reports and when?*

(1) If you are a user facility, you must submit MDR reports to:

(i) The manufacturer and to us no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or

(ii) The manufacturer no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. If the manufacturer is not known, you must submit this report to us.

(2) If you are an importer, you must submit MDR reports to:

(i) The manufacturer and to us, no later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or

(ii) The manufacturer, no later than 30 calendar days after receiving

information that a device you market 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.

(3) If you are a manufacturer, you must submit MDR reports to us:

(i) No later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury or

(ii) No later than 30 calendar days after the day that you become aware of information that reasonably suggests a device 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; or

(iii) Within 5 work days if required by § 803.53.

(c) *What kind of information reasonably suggests that a reportable event has occurred?*

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in § 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MedWatch Medical Device Reporting Code Instruction Manual contains adverse event codes for use with Form FDA 3500A. You may obtain the coding manual from FDA's Web site at: <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/>

[FormsandInstructions/default.htm](http://www.fda.gov/oc/FormsandInstructions/default.htm); and from the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993-0002, FAX: 301-847-8149, or email to DSMICA@fda.hhs.gov.

(b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.

§ 803.22 What are the circumstances in which I am not required to file a report?

(a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.

(b) You are not required to submit a medical device report if:

(1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 803.18.

(2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.

§ 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.

Subpart C—User Facility Reporting Requirements

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

(a) You must submit reports to the manufacturer or to us, or both, as specified in paragraphs (a)(1) and (a)(2) of this section as follows:

(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(b).

(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 (b).

(b) *What information does FDA consider "reasonably known" to me?* You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable followup within your facility. You are not required to evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.

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

You must include the following information in your report, if reasonably known to you, as described in § 803.30(b). These types of information correspond generally to the elements of Form FDA 3500A:

(a) Patient information (Form FDA 3500A, Block A). You must submit the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:

- (1) Identification of adverse event or product problem;
- (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
 - (i) A life-threatening injury or illness;
 - (ii) A disability resulting in permanent impairment of a body

function or permanent damage to a body structure; or

(iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of this report;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Description of other relevant history, including preexisting medical conditions.

(c) Device information (Form FDA 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.)

(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the manufacturer or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) User facility information (Form FDA 3500A, Block F). You must submit the following:

(1) An indication that this is a user facility report (by marking the user facility box on the form);

(2) Your user facility number;

(3) Your address;

(4) Your contact person;

(5) Your contact person's telephone number;

(6) Date that you became aware of the event (month, day, year);

(7) Type of report (initial or followup); if it is a followup, you must include the report number of the initial report;

(8) Date of your report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to the "MedWatch Medical Device Reporting Code Instructions");

(11) Whether a report was sent to us and the date it was sent (month, day, year);

(12) Location where the event occurred;

(13) Whether the report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address, if available.

§ 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 Form FDA 3419. You must submit an annual report by January 1, of each year. You may obtain this form from the following sources:

(1) On the Internet at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080796.pdf> or

(2) Division of Small Manufacturers, International and Consumer Assistance, Office of Communication and Education, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993-0002, by email: DSMICA@fda.hhs.gov, FAX: 301-847-8149, or telephone: 800-638-2041.

(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., 1234567890–2011–0001 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.

Subpart D—Importer Reporting Requirements

§ 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 sent to the Agency 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. Reports to manufacturers may be made in accordance with § 803.11(b).

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

You must include the following information in your report, if the information is known or should be known to you, as described in § 803.40. These types of information correspond generally to the format of Form FDA 3500A:

(a) Patient information (Form FDA 3500A, Block A). You must submit the following:

- (1) Patient name or other identifier;
- (2) Patient age at the time of event, or date of birth;
- (3) Patient gender; and
- (4) Patient weight.

(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:

- (1) Identification of adverse event or product problem;
- (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:

- (i) A life-threatening injury or illness;
- (ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
- (iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

- (3) Date of event;
- (4) Date of this report;
- (5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

- (6) Description of relevant tests, including dates and laboratory data; and
- (7) Description of other relevant patient history, including preexisting medical conditions.

(c) Device information (Form FDA 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 explanation (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, and 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.)

(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to the manufacturer, user facility, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to us, if known.

(e) Importer information (Form FDA 3500A, Block F). You must submit the following:

(1) An indication that this is an importer report (by marking the importer box on the form);

(2) Your importer report number;

(3) Your address;

(4) Your contact person;

(5) Your contact person's telephone number;

(6) Date that you became aware of the event (month, day, year);

(7) Type of report (initial or followup). If it is a followup report, you must include the report number of your initial report;

(8) Date of your report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA MedWatch Medical Device Reporting Code Instructions);

(11) Whether a report was sent to us and the date it was sent (month, day, year);

(12) Location where event occurred;

(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address, if available.

Subpart E—Manufacturer Reporting Requirements

§ 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:

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

(2) Has malfunctioned and 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.

(b) What information does FDA consider “reasonably known” to me?

(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:

(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;

(ii) Any information in your possession; or

(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.

(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

(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).

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

You must include the following information in your reports, if known or reasonably known to you, as described in § 803.50(b). These types of information correspond generally to the format of Form FDA 3500A:

(a) Patient information (Form FDA 3500A, Block A). You must submit the following:

(1) Patient name or other identifier;
(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Form FDA 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:

(i) A life-threatening injury or illness;

(ii) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of this report;

(5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including preexisting medical conditions.

(c) Device information (Form FDA 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, and 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.)

(d) Initial reporter information (Form FDA 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the user facility or importer;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to us, if known.

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

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

(2) Your contact person'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.

(f) Device manufacturer information (Form FDA 3500A, Block H). You must submit the following:

(1) Type of reportable event (death, serious injury, malfunction, etc.);

(2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc);

(3) If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation;

(4) Device manufacture date (month, day, year);

(5) Whether the device was labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MedWatch Medical Device Reporting Code Instructions);

(7) Whether remedial action was taken and the type of action;

(8) Whether the use of the device was initial, reuse, or unknown;

(9) Whether remedial action was reported as a removal or correction under section 519(f) of the Federal Food, Drug, and Cosmetic Act, and if it was, provide the correction/removal report number; and

(10) Your additional narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or importer report, including any event codes that were not

reported, or information corrected on these forms after your verification;

(ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and

(iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

§ 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:

(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis or

(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

§ 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;

(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number

of any report on which your report was based), if applicable; and

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

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with § 803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

§ 803.58 [Amended]

3. Section 803.58 is stayed indefinitely.

Dated: February 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-03279 Filed 2-13-14; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket No. OSHA 2012-0029]

RIN 1218-AC89

Hawaii State Plan for Occupational Safety and Health; Operational Status Agreement Revisions

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This document announces revisions to the Operational Status Agreement between the Occupational Safety and Health Administration (OSHA) and the Hawaii State Plan, which specifies the respective areas of federal and state authority, and under which Hawaii will reassume additional coverage.

DATES: Effective February 14, 2014.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Francis Meilinger, OSHA Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-1999; email: meilinger.francis2@dol.gov.

For general and technical information: Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, Room N-3700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210; telephone: (202) 693-2200; email: kalinowski.doug@dol.gov.

SUPPLEMENTARY INFORMATION:

Background

Hawaii administers an OSHA-approved state plan to develop and enforce occupational safety and health standards for public and private sector employers, pursuant to the provisions of Section 18 of the Occupational Safety and Health Act (the Act). Pursuant to Section 18(e) of the Act, OSHA granted Hawaii “final approval” effective April 30, 1984 (49 FR 19182). A final approval determination results in the relinquishment of federal concurrent enforcement authority in the state with respect to occupational safety and health issues covered by the plan. 29 U.S.C. 667(e).

From 2009–2012, the Hawaii State Plan faced major budgetary and staffing restraints that significantly affected its program. Therefore, the Hawaii Director of Labor and Industrial Relations requested a temporary modification of the state plan’s approval status from final approval to initial approval, to permit exercise of supplemental federal enforcement activity and to allow Hawaii sufficient time and assistance to strengthen its state plan. On June 22, 2012, a Notice of Proposed Rulemaking was published and on September 21, 2012, OSHA published a Final Rule in the **Federal Register** (77 FR 58488) that modified the Hawaii State Plan’s “final approval” determination under Section 18(e) of the Act, transitioned the Plan to “initial approval” status under Section 18(b) of the Act, and reinstated concurrent federal enforcement authority over occupational safety and health issues in the private sector. That