



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2918]

Pilot Program for Medical Device Reporting on Malfunctions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is soliciting nominations for participation in a pilot program for the submission of medical device reports for malfunctions of class I devices and certain class II devices in summary format on a quarterly basis. Under the Medical Device Reporting on Malfunctions pilot program, FDA intends to work with manufacturers to identify candidates for the pilot program and intends to continue to accept nominations until candidates for the pilot program have been selected.

DATES: FDA will begin accepting nominations for participation in the voluntary pilot program on [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], and intends to continue to accept nominations until candidates for the pilot program have been selected. See section II for instructions on how to participate in the voluntary pilot program.

FOR FURTHER INFORMATION CONTACT: William C. Maloney, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 3236, Silver Spring, MD 20993-0002, [227pilot@fda.hhs.gov](mailto:227pilot@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85), amended section 519(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(a)), relating to the reporting of device malfunctions to FDA under part 803 (21 CFR part 803). Specifically, FDAAA amended the FD&C Act to require that medical device reports of malfunctions for class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining--with the exception of any type of class I or II device which FDA has, by notice, published in the Federal Register or by letter to the person who is the manufacturer or importer of the device, indicated should be subject to part 803 in order to protect the public health--be submitted in accordance with the criteria established by FDA (section 519(a)(1)(B)(ii) of the FD&C Act).<sup>1</sup> The criteria must require the reports to be in summary form and made on a quarterly basis (section 519(a)(1)(B)(ii) of the FD&C Act).

FDA is considering the development of malfunction reporting criteria for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act. In the interim, FDA clarified that all manufacturers of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining, must continue to report in full compliance with part 803 (76 FR 12743 at 12744, March 8, 2011).

The malfunction reporting requirements for class III devices and those class II devices that are permanently implantable, life supporting, or life sustaining were not altered by FDAAA. Under the amended section 519(a) of the FD&C Act, device manufacturers are to continue to submit malfunction reports in accordance with part 803 for all class III devices and for those class II devices that are permanently implantable, life supporting, or life sustaining, unless FDA

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<sup>1</sup> In light of section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) and the Secretary of Health and Human Services' (the Secretary's) delegation to the Commissioner of Food and Drugs, statutory references to "the Secretary" have been changed to "FDA" or the "Agency" in this document.

grants an exemption or variance from, or an alternative to, a requirement under such regulations under § 803.19 (section 519(a)(1)(B)(i) of the FD&C Act).

In addition, under section 519(a) of the FD&C Act, as amended by FDAAA, there is no change to the obligation for an importer to submit malfunction reports to the manufacturer in accordance with part 803 for devices that it imports into the United States (section 519(a)(1)(B)(iii) of the FD&C Act).

FDA intends to use the information learned and experiences gained from the pilot program to develop the malfunction reporting criteria for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act.

## II. Pilot Program for Medical Device Reporting (MDR) on Malfunctions

FDA has developed this pilot program for manufacturers interested in submitting malfunction reports for certain devices in a summary format on a quarterly basis. This notice provides: (1) The guiding principles underlying the pilot program, (2) the conditions for participation in the pilot program, (3) a description of the pilot program, (4) the eligibility criteria for the pilot program, (5) the procedures that FDA intends to follow in the pilot program, (6) the manufacturer notification process, (7) FDA's review process for the summary reports, (8) the duration of the pilot program, and (9) FDA's evaluation process for the pilot program.

### A. Guiding Principles

The following basic principles underlie the Medical Device Reporting on Malfunctions pilot program described in this notice. FDA intends for these principles to create a common understanding between the manufacturer and FDA about the goals and parameters of this pilot program.

1. FDA is exploring a possible approach to summary reporting of device malfunctions on a quarterly basis under the pilot program (as illustrated in the case examples in this notice in section II.C. Description of the Program) that would allow FDA to collect sufficient detail to effectively monitor the devices subject to section 519(a)(1)(B)(ii) of the FD&C Act and protect the public health.
2. The data received in this pilot should contain details sufficient to understand the device-related malfunctions. A narrative text should be provided to include a summary of the malfunction events, the results of the manufacturer's investigation of the reported malfunctions, including the type of any remedial action taken or an explanation of why remedial action was not taken, and any additional information that would be helpful to understand how the manufacturer addressed the malfunctions summarized in the report.
3. As the summary information collected under this pilot represents a subset of the detailed information collected under § 803.52, FDA intends to use the existing electronic Medical Device Reporting (eMDR) infrastructure for the summary reports.
4. All summary MDR reports<sup>2</sup> will appear in the Manufacturer and User Facility Device Experience (MAUDE) database, which is publically available.

#### B. Conditions

1. Under § 803.19, manufacturers who are accepted into the program will be granted an exemption or variance from, or alternative to, the reporting requirements under §§ 803.50(a) and 803.52 for those malfunction events associated with the devices selected for the pilot. Other reportable events involving the devices selected for the

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<sup>2</sup> Any information in the report that is protected from public disclosure under the Freedom of Information Act (FOIA) will be redacted prior to the release of the report.

- pilot must be reported to FDA within the mandatory 30-calendar day timeframe on Form FDA 3500A, as required by §§ 803.50(a) and 803.52, or within the 5-work day timeframe as required by § 803.53. Additional information and instructions will be provided to manufacturers accepted into the pilot.
2. A candidate is not precluded from withdrawing from the pilot program at any time and returning to the individual reporting requirements of §§ 803.50(a) and 803.52.
  3. Due to FDA resource issues, FDA intends to limit the pilot program to no more than nine (9) candidates.
  4. At its discretion, FDA may withdraw a manufacturer from the pilot program, for reasons including, but not limited to, any violations of the FD&C Act, failure to follow the instructions of the pilot program, or if FDA obtains information after the manufacturer is accepted to the pilot program that the manufacturer is not an appropriate candidate for the program as described in this notice in section II.D. Appropriate Candidates. Withdrawal from the pilot program will result in a return to the individual reporting requirements of §§ 803.50(a) and 803.52.
  5. At its discretion, FDA may modify specific details regarding the pilot if needed. Any such changes will be communicated directly to the candidates of the pilot program.

### C. Description of the Program

Candidates of the pilot program will submit Form FDA 3500A reports in electronic reporting format on a quarterly basis. For purposes of the pilot, “quarterly basis” is defined as a three (3) month period. Each submission should represent a summary of malfunction events received for a unique device problem code or set of codes within the quarterly timeframe, and for a particular device model number and/or catalog number. Device malfunctions that are

summarized in one report should not be duplicated in any other submissions within the same quarterly timeframe.

Summary reports should include the following information collected on Form FDA 3500A in electronic format:

SECTION B.5: Describe Event or Problem--The device event narrative should include a description of the nature of the events (being as specific as possible); and if available, a range of patient age and weight, and a breakdown of patient gender. The first sentence of the device event narrative should include the following sentence:

“This report summarizes <NOE> XXX </NOE> malfunction events” where XXX is replaced by the number of malfunction events being summarized.

SECTION D.2 and D.2.b: Common Device Name and Procode--Enter the common name of the device and the product code.

SECTION D.3: Manufacturer Name, City and State--Enter the manufacturer name, city and state where the manufacturer is located.

SECTION D.4: Device Identification--Enter the model or catalog number for the device being summarized in the MDR report.

SECTION G.1: Contact Office (and Manufacturing Site for Devices)--Enter the name and address of the manufacturer reporting site [contact office], including contact name for the report submitted. Enter the name and address of the manufacturing site for the device, if different from the contact office.

SECTION G.2: Phone Number--Enter the phone number for the contact office.

SECTION H.1: Type of Reportable Event--Check “Malfunction” in this box.

SECTION H.6: Event Problem and Evaluation Codes--Enter the device problem code(s), including any codes received from a user facility or importer report provided in Section F.10 of Form FDA 3500A. Enter "9999" as the first device problem code to identify the report as a summary malfunction report. Enter the evaluation code(s) for the categories of method, results, and conclusions. Enter a conclusion code(s) even if the device was not evaluated.

SECTION H.10: Additional Manufacturer Narrative--Provide a summary of the results of your investigation of the reported malfunctions, including the type of any remedial action taken or an explanation of why remedial action was not taken, and any additional information that would be helpful to understand how you addressed the malfunction events summarized in the report. Also enter a breakdown of the malfunction events summarized in the report, including the number of devices that were returned to you; the number of devices that were labeled for single use (if any); and the number of devices that were reprocessed and re-used (if any).

NOTE: All reportable adverse events which result in a serious injury or death; and/or necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health, are excluded from this pilot program. In addition, for reference here is the link to the on-line version of the Form FDA 3500A:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.pdf>.

Case Examples: The following examples are meant to illustrate the format for how malfunction reports submitted under this pilot will be captured. All of these examples are for

class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining. These examples do not address interpretation of these reportable events.

Case Scenario #1: Multiple malfunction reports for the same device problem.

A manufacturer receives 50 similar reports within the quarterly timeframe indicating that model XYZ pump experienced an air detected set alarm, which interrupted delivery. The alarms may have been a false alarm. These events were received from various sources. Of the 50 adverse events, 46 did not involve patients, and 4 involved patients with no reported injuries or deaths. None of these events necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health. The XYZ pumps were recently retrofitted with a new user interface software model V.2.04.12.

Report for Case #1: A single summary MDR report is to be submitted to FDA through eMDR:

- B.5: This report summarizes <NOE> 50 </NOE> malfunction events. A review of the events indicated that model XYZ pump experienced an air detected set alarm, which interrupted delivery. The alarms may have been a false alarm. These reports were received from various sources. Of the 50 events, 46 did not involve patients, and 4 involved patients with no patient consequences. The four patients ranged from 25-32 years of age and 130-250 lbs. Of the reported patients, one was male and three were female. The XYZ pumps were recently retrofitted with a new user interface software model V.2.04.12.
- D.2: Infusion Pump
- D.2.b: FRN



- D.3: ABC Company, 123 Baker Street, Anywhere, MD, USA
- D.4: Model XYZ
- G.1: Mr. X, ABC company, 123 Baker Street, Anywhere, MD, USA
- G.2: 301-555-0001
- H.1: Malfunction
- H.6: Device Codes: 9999 (Summary Malfunction); 1008 (Air Leak)
- H.6: Manufacturer Method Codes: 10 (Actual Device Evaluated); 38 (Visual Inspection)
- H.6: Manufacturer Results Code: 549 (Air pump assembly)
- H.6: Manufacturer Evaluation Conclusion Codes: 52 (Device was out of calibration)
- H.10: For 40 of the 50 reported events, the devices were returned to ABC, and their operating condition was confirmed by service. The cause of the malfunction was determined to be a faulty pump head module. To correct the condition, the pump head modules were replaced.

Case Scenario #2: Multiple malfunction reports that have two device problems:

A manufacturer receives 100 malfunction reports within the quarterly timeframe that include two types of device malfunctions that are related to a specific model (XYZ, Version 2) of a powered AC bed: (1) 75 events involve a broken weld near where the motor attaches; and (2) 55 events involve a screw that attaches the bed rail to the mounting bracket on the bed, which snapped. Some of the events involve both types of device malfunctions. None of the events involve patients. None of the events necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

Reports for Case #2: Under this pilot, a unique device problem code or set of codes for a particular device model number and/or catalog number that are summarized in one report should not be duplicated in any other submissions within the same quarterly timeframe.

As a result, there are three categories of reports for this scenario--(1) 45 events that involve broken welds only; (2) 25 events that involve broken screws only; and (3) 30 events that involve both broken welds and broken screws. Therefore, three summary reports will need to be submitted to FDA through eMDR.

Report #1:

- B.5: This report summarizes <NOE> 45 </NOE> malfunction events. A review of the events indicated that model XYZ experienced broken welds near where the motor attaches to the powered AC beds. No patients were involved.
- D.2: AC Powered Beds
- D.2.b: FNL
- D.3: ABC company, 123 Baker Street, Anywhere, MD, USA
- D.4: Model XYZ
- G.1: Mr. X, ABC Company, 123 Baker Street, Anywhere, MD, USA
- G.2: 301-555-0001
- H.1: Malfunction
- H.6: Device Codes: 9999 (Summary Malfunction); 1069 (Break); 3195 (Weld)
- H.6: Manufacturer Method Codes: 10 (Actual Device Evaluated); 38 (Visual Inspection)
- H.6: Manufacturer Results Code: 170 (Manufacturing process problem)

- H.6: Manufacturer Evaluation Conclusion Codes: 12 (Design deficiency)
- H.10: To correct the condition, the beds were taken out of service.

Report #2:

- B.5: This report summarizes <NOE> 25 </NOE> malfunction events. A review of the events indicated that a screw that attaches the bed rail to the mounting bracket on the bed is snapping on model XYZ. No patients were involved.
- D.2: AC Powered Beds
- D.2.b: FNL
- D.3: ABC company, 123 Baker Street, Anywhere, MD, USA
- D.4: Model XYZ
- G.1: Mr. X, ABC Company, 123 Baker Street, Anywhere, MD, USA
- G.2: 301-555-0001
- H.1: Malfunction
- H.6: Device Codes: 9999 (Summary Malfunction); 1069 (Break); 568 (Screw)
- H.6: Manufacturer Method Codes: 10 (Actual Device Evaluated); 38 (Visual Inspection)
- H.6: Manufacturer Results Code: 170 (Manufacturing process problem)
- H.6: Manufacturer Evaluation Conclusion Codes: 12 (Design deficiency)
- H.10: To correct the condition, the beds were taken out of service temporarily. A technician was dispatched to replace the screw. Load testing was applied to verify bed rail performance.

Report #3:

- B.5: This report summarizes <NOE> 30 </NOE> malfunction events. A review of the events indicated that a screw that attaches the bed rail to the mounting bracket on the AC powered bed failed causing the bed rail to detach and collide with the beam near where the motor attaches. The force of impact caused a broken weld to form near the motor attachment on the AC powered bed. No patients were involved.
- D.2: AC Powered Beds
- D.2.b: FNL
- D.3: ABC Company, 123 Baker Street, Anywhere, MD, USA
- D.4: Model XYZ
- G.1: Mr. X., ABC Company, 123 Baker Street, Anywhere, MD, USA
- G.2: 301-555-0001
- H.1: Malfunction
- H.6: Device Codes: 9999 (Summary Malfunction); 1069 (Break); 3195 (Screw); 568 (Weld)
- H.6: Manufacturer Method Codes: 10 (Actual Device Evaluated); 38 (Visual Inspection)
- H.6: Manufacturer Results Code: 170 (Manufacturing process problem)
- H.6: Manufacturer Evaluation Conclusion Codes: 12 (Design deficiency)
- H.10: To correct the condition, the beds were taken out of service. Technicians have examined the beds and have opened up a Corrective and Preventive Action (CAPA) to address the design issue.

#### D. Appropriate Candidates

Appropriate candidates for the pilot program are manufacturers who:

1. Are currently submitting reports to FDA using the paper Form FDA 3500A or the electronic MDR (eMDR) format.
2. Manufacture class I devices and/or those class II devices that are not permanently implantable, life supporting, or life sustaining.
3. Currently use or are willing to use eMDR to submit summary malfunction reports to the FDA during the pilot period.
4. Are in compliance with the Medical Device Reporting regulation in 21 CFR part 803.

#### E. Procedures

##### 1. Nomination

A manufacturer of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining may nominate themselves for participation in the pilot program by submitting a nomination to [227pilot@fda.hhs.gov](mailto:227pilot@fda.hhs.gov). FDA intends to acknowledge receipt of nominations via return email. The following information will assist FDA in processing and responding to nominations:

- Name of manufacturer
- Registration number
- Contact name, address, phone number, and email address
- Model or catalog number for the device(s) that you are requesting to include in the pilot, and

- Product classification code for the device(s) that you are requesting to include in the pilot. You may access the Product Classification Code database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

## 2. FDA Consideration

Acceptance of nominations will start 2 weeks following the publication date of this Federal Register notice. Because only a limited number of candidates are needed, FDA will use its discretion in choosing candidates based on the eligibility criteria in this Federal Register notice in section II.D. Appropriate Candidates, the needs of the pilot to include a diversity of manufacturers with regard to device type (including in vitro diagnostic devices), and expected number of malfunction events. FDA may contact the manufacturer to request supplemental information if this information is needed in order to complete our review of the request. The manufacturer must provide the supplemental information within 15 days of FDA's request; otherwise, the Agency will consider the nomination withdrawn.

### F. Manufacturer Notification

FDA intends to notify manufacturers who are selected for this pilot program within 45 days from receiving their nomination or any supplemental information requested by FDA. Once FDA has selected the candidates for this pilot, FDA will notify subsequent applicants by email that the nomination period has closed.

### G. FDA Review

All reports received under the pilot program will be reviewed and processed in the same manner as individual medical device reports that are submitted under part 803. A version of the report releasable under FOIA will be accessible through the public MAUDE database.

#### H. Duration of the Pilot

FDA intends for the pilot program to run for 2 calendar quarters for each candidate and will continue until the 2 calendar quarters have been completed for all candidates. At its discretion, FDA may terminate the pilot program before the close of this period, or FDA may extend the pilot program beyond the 2 calendar quarters. The decision to terminate or extend the pilot will be announced in the Federal Register.

#### I. Evaluation

FDA intends to evaluate all information and feedback received from the candidates and to use the information and experiences gained from the pilot program to develop criteria for summary reporting on a quarterly basis for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act.

#### III. Paper Reduction Act of 1995

This notice refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; the collections of information in Form FDA 3500A have been approved under OMB control number 0910-0291.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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