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Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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Preface

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Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance document to help manufacturers better understand and use the Voluntary Malfunction Summary Reporting (VMSR) Program. It is intended to further explain, but not change, the conditions of the VMSR Program.

This guidance describes and clarifies several aspects of the VMSR Program, including the FDA's approach to determining the eligibility of product codes for the program and the conditions for submitting medical device reports (MDRs) for device malfunctions in summary format under the program. Consistent with the goals outlined in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter,[1] the VMSR Program is intended to streamline reporting of device malfunctions. The program began in 2018 when FDA issued a notification in the Federal Register of an order granting an alternative under 21 CFR 803.19 that permits manufacturers of devices in eligible product codes to report certain device malfunction MDRs in summary form on a quarterly basis, subject to the conditions of the alternative (Final VMSR Notice, 83 FR 40973[2]).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of

[1] Available at https://www.fda.gov/media/102699/download.
[2] Available at https://www.federalregister.gov/d/2018-17770.

the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Each year, FDA receives over two million MDRs of suspected device-related deaths, serious injuries, and malfunctions. The MDR Program is one of the postmarket surveillance tools that FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments.[3] Malfunction reports represent most of the MDRs received by FDA on an annual basis. As part of FDA's postmarket surveillance for devices, the Agency reviews the MDRs submitted by both mandatory and voluntary reporters.

FDA has determined that for many devices, it is appropriate to permit manufacturers to submit malfunction summary reports on a quarterly basis, for certain malfunctions related to devices with certain product codes, instead of individual, 30-day malfunction reports. FDA's VMSR Program is intended to yield benefits for FDA, the public, and manufacturers, such as increasing transparency for the public, helping FDA to process certain malfunction reports more efficiently, allowing both FDA and the public to identify malfunction trends more readily, and reducing the burden on manufacturers.

MDR requirements for manufacturers are set forth in section 519 of the FD&C Act and 21 CFR Part 803. Among other things, 21 CFR Part 803 requires that a manufacturer submit a report of an individual adverse event when it becomes aware of information, from any source, which reasonably suggests that one of its marketed devices malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur (21 CFR 803.10(c)(1) and 803.50(a)(2)). Throughout this guidance document, FDA refers to such malfunctions as "reportable malfunctions" or "reportable malfunction events." Under 21 CFR Part 803, such reports generally must be submitted to FDA within 30 calendar days after the day the manufacturer becomes aware of the reportable malfunction event (21 CFR 803.10(c)(1) and 803.50). Under some circumstances an MDR is required to be submitted within 5 work days after the day the manufacturer becomes aware of the need to submit such a report (see 21 CFR 803.10(c)(2) and 803.53).

The FDA Amendments Act of 2007 (FDAAA[4]) amended section 519(a) of the FD&C Act related to the reporting of device malfunctions. FDAAA did not alter the malfunction reporting requirements for class III devices and those class II devices that are permanently implantable, life supporting, or life sustaining. Under section 519(a)(1)(B)(i) of the FD&C Act, as amended by FDAAA, manufacturers of such devices must continue to submit malfunction reports in accordance with 21 CFR Part 803 (or successor regulations), unless FDA grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to 21 CFR 803.19. FDAAA also amended the FD&C Act to require that manufacturers submit malfunction

[3] For general information on the MDR Program, see FDA's website at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.
[4] Pub. L. 110-85.

MDRs for class I and those class II devices that are not permanently implantable, life supporting, or life sustaining—other than any type of class I or II device that 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—in accordance with criteria established by FDA. The criteria require those reports to be in summary form and made on a quarterly basis. See section 519(a)(1)(B)(ii) of the FD&C Act. In the Federal Register of March 8, 2011 (76 FR 12743), FDA explained that, pending further notice from the Agency, all class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining would remain subject to individual reporting requirements under Part 803 to protect the public health, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act. Consequently, unless granted an exemption, variance, or alternative, manufacturers of those devices have continued to be required to submit individual malfunction reports under Part 803. FDA began a pilot program in 2015 for the submission of MDRs of certain malfunctions in a summary format on a quarterly basis (80 FR 50010[5]).

In the MDUFA IV Commitment Letter, FDA committed to streamlining MDR requirements for malfunction reporting.[6] To help meet the MDUFA IV commitment, FDA issued a notification in 2017 (82 FR 60922[7]) outlining FDA's proposal to grant an alternative under 21 CFR 803.19 to permit manufacturer reporting of certain device malfunctions in summary format on a quarterly basis, subject to certain conditions, and requested public comment. FDA granted that alternative in 2018 to manufacturers of devices in certain product codes and provided notice of an order granting that alternative in the Federal Register (Final VMSR notice, 83 FR 40973[8]).

The FDA implemented the VMSR Program only after the Agency had conducted the 2015 pilot program that demonstrated the value of the program to public health, better use of Agency resources, and promotion of public transparency.

As explained when it proposed the VMSR Program (82 FR 60922[9]), and consistent with our VMSR Program experience to date, FDA believes that bundling "like events" together into a single summary report description has benefits for manufacturers, FDA, and the public. For many manufacturers, we expect this approach will greatly reduce the volume of reports that the manufacturer needs to submit to FDA. As more information is received in a streamlined manner, it can facilitate a more efficient understanding by FDA of malfunction issues. For the public, summary reports may make malfunction event trends for a particular device more readily transparent. We believe increased manufacturer participation in the program will enhance these benefits.

[5] Available at https://www.federalregister.gov/d/2015-20309.
[6] See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download.
[7] Available at https://www.federalregister.gov/d/2017-27650.
[8] Available at https://www.federalregister.gov/d/2018-17770.
[9] Available at https://www.federalregister.gov/d/2017-27650.

III. Principles of Voluntary Malfunction Summary Reporting

In the Final VMSR notice, FDA identified the following overarching principles for summary reporting of malfunctions under the VMSR Program:

1. The collection of information in summary format should allow FDA to collect sufficient detail to understand reportable malfunction events.

2. To increase efficiency, summary malfunction reporting should occur in a common format for the electronic reporting system used.

3. Information about reportable malfunctions should be transparent to FDA and to the public, regardless of whether the information is reported as an individual MDR or a summary report.[10] Information contained in a summary malfunction report that is protected from public disclosure under applicable disclosure laws is redacted prior to release of the report.

4. Manufacturers should communicate information regarding an imminent hazard[11] at the earliest time possible.

5. Summary reporting is meant to streamline the process of reporting malfunctions. It does not change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers. For example, manufacturers participating in the VMSR Program remain subject to requirements for establishing and maintaining MDR event files under 21 CFR 803.18. In addition, under the Quality System regulation, manufacturers must evaluate, review, and investigate any complaint that represents an MDR reportable event (see 21 CFR 820.198).

6. Summary reporting information should not be duplicative of information received through other MDR reporting processes.

IV. Voluntary Malfunction Summary Reporting Program Eligibility and Scope

[10] Consistent with this principle, summary reports submitted by manufacturers under the VMSR Program are made available to the public in the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. For more information about FDA's procedures for disclosing information submitted under 21 CFR Part 803, see 21 CFR 803.9.

[11] For the purposes of this overarching principle and consistent with FDA's 2018 notice of granting an alternative that permits manufacturer reporting of certain device malfunction MDRs in summary form on a quarterly basis, (Final VMSR notice, 83 FR 40793), FDA intends "imminent hazard" to capture situations in which a device poses a significant risk to health and creates a public health situation that should be addressed immediately to prevent injury.

The VMSR Program permits manufacturers of devices within eligible product codes to report certain device malfunction MDRs in summary form quarterly, as an alternative to submitting individual MDRs for reportable malfunction events. Manufacturers may "self-elect" to participate in the VMSR Program by submitting summary malfunction reports for eligible product codes, and do not need to submit a separate application to FDA to participate. Participation in the VMSR Program is not required, and manufacturers of devices within eligible product codes may continue submitting individual, 30-day malfunction reports in compliance with 21 CFR 803.50 and 803.52, if a manufacturer chooses to do so. FDA updates the Agency's searchable Product Classification Database[12] to reflect product codes eligible for participation in the VMSR Program.

The VMSR Program helps enhance the FDA's capacity to effectively monitor the safety and effectiveness of devices. The VMSR Program's conditions help ensure that manufacturers submit sufficient information to allow FDA to detect potential safety issues and identify malfunction trends, while the summary reports provide information on malfunctions in a more efficient format. The program thus enables FDA to be more effective in its device safety oversight. The following sub-sections are intended to explain the factors FDA generally considers when determining if a product code is eligible for the VMSR Program and to clarify event types that are not covered by the VMSR Program. Further clarification on the reporting conditions of the Program are discussed under Section V.

A. Product Code Eligibility

When FDA implemented the VMSR Program in 2018, the Agency evaluated all device product codes, for all device classes, to determine Program eligibility, including product codes for device-led combination products. As noted in FDA's Final VMSR notice, product codes that have been in existence for fewer than two years generally are not eligible, unless the new product code was created solely for administrative reasons.[13] In FDA's experience, this two-year period is important for having more timely, detailed information to monitor malfunction events. FDA continues to evaluate new product codes after they have been in existence for two years to determine whether it is appropriate for those product codes to be eligible for the VMSR Program. FDA also periodically evaluates ineligible product codes for eligibility changes.

(1) Periodic Evaluation

As stated in section VI of the Final VMSR notice (83 FR 40973[14]), the FDA intends to periodically assess and update the eligibility of product codes for the VMSR Program. As part of determining eligibility of product codes, FDA intends to consider the device's benefit-risk profile and available postmarket safety information, particularly related to device malfunctions. The Agency generally considers whether quarterly, summary reporting of device malfunctions, in accordance with the conditions of the VMSR Program, would allow FDA to timely identify

[12] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm. After searching, the field "Summary Malfunction Reporting" specifies the eligibility status of a particular product code.
[13] Final VMSR notice (83 FR 40973).
[14] Available at https://www.federalregister.gov/d/2018-17770.

potential new or increased safety concerns for devices within the product code at issue. If FDA determines that a product code is eligible, FDA intends to update the Product Classification Database[15] accordingly.

In analyzing available postmarket safety information for devices within a certain product code, the Agency also intends to consider, among other things, the frequency of reported serious injuries and deaths, the number of 5-day reports, and whether the product code has any class I or II recalls. The Agency may also consider the types of malfunctions that occur in a given product code, the complexity of those malfunctions, and the ability for FDA to understand their root cause. FDA may also consider whether the product code is associated with recent, ongoing, or potential public health issues that may necessitate the detail and frequency of individual malfunction reporting for FDA to identify and better characterize new or persistent safety issues. When a public health issue necessitates close monitoring of individual adverse events associated with certain devices, the Agency may determine that summary reporting under the VMSR Program is not appropriate for product codes for those devices. For example, FDA has determined that certain reusable devices may have a high risk of infection if they are not adequately reprocessed. Devices listed in Appendix E of the FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,"[16] are examples of device types associated with such risks, and FDA has determined for these product codes that summary reporting was not appropriate.

FDA's eligibility determinations are intended to follow the overarching principles of the VMSR Program described in Section III above, to help ensure that summary reporting of malfunctions for all eligible product codes allows FDA to collect sufficient information to understand the reported events, that information can be provided in a common format and is transparent to FDA and to the public, that imminent hazards will be communicated at the earliest time possible, and that summary reporting for devices in any eligible product code streamlines the process of reporting malfunctions.

(2) Eligibility Requests

Manufacturers may send a request under 21 CFR 803.19(b) for a product code or multiple product codes to be considered for eligibility in the VMSR Program and for manufacturers of devices within such product code(s) to be granted the same summary reporting alternative for reportable malfunction events associated with those devices. FDA intends to periodically review manufacturer requests and update the eligibility of product codes for the VMSR Program based on requests received.

For requests emailed to FDA at MDRPolicy@fda.hhs.gov, manufacturers should submit the following information:

- The firm's name, address, registration number;
- The contact person's name, telephone number, and email address;

[15] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.

[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

- Complete device identification and description, including product code and review panel;
- A complete statement of the request and justification for the request, including a discussion of known information related to the product code's benefit-risk profile and postmarket safety, and why individual malfunction reporting is not necessary; and
- As part of the justification for the request, a manufacturer should provide a copy of any prior FDA correspondence (including the references to the Document ID #) regarding device eligibility status and describe any actions taken to address any issues noted in prior FDA correspondence regarding device eligibility for participation in the VMSR Program.

B. Event Types and Reporters Not Covered by the VMSR Program

As described above, the VMSR Program is generally available for manufacturers of devices within eligible product codes. However, the following types of MDR reportable events and entities subject to MDR reporting requirements are outside the scope of the VMSR Program alternative granted under 21 CFR 803.19:

- Reportable death and serious injuries;[17]
- A reportable malfunction is associated with a 5-day report, as required in 21 CFR 803.53; and
- Importers and device user facilities, because 21 CFR Part 803 does not require either entity to report malfunctions to FDA.[18]

V. VMSR Program Conditions

A. Individual Reporting Conditions

As previously discussed, manufacturers participating in the VMSR Program submit summary malfunction reports under an alternative to certain MDR reporting requirements that FDA has granted to manufacturers of devices within eligible product codes. When FDA grants such modifications to the MDR reporting requirements, we may impose other reporting requirements to ensure the protection of public health (21 CFR 803.19(c)). Accordingly, as set forth in the

[17] See section IV.A of the Final VMSR notice (83 FR 40973). The alternative granted under 21 CFR 803.19 to manufacturers participating in the VMSR Program does not alter the requirement that reportable deaths and serious injuries must be reported to FDA within the mandatory 30-calendar day timeframe, under 21 CFR 803.50 and 803.52, or within the 5-work day timeframe under 21 CFR 803.53, as applicable. Thus, if a manufacturer participating in the VMSR Program becomes aware of information reasonably suggesting that a device that it markets may have caused or contributed to a death or serious injury, then the manufacturer must submit an individual MDR for that event because it involves a reportable death or serious injury.

[18] See section IV of the Final VMSR notice, footnote 1 (83 FR 40973). Importers are required to report malfunctions to the manufacturer under 21 CFR 803.40(b). Unlike manufacturers and importers, device user facilities are not required under 21 CFR Part 803 to submit malfunction reports to any entity.

Final VMSR notice (83 FR 40973[19]), FDA imposed several conditions that manufacturers must follow if they elect to participate in the VMSR Program under the alternative.[20] These include conditions for "individual reporting," submission of supplemental reports, and the format and submission schedule for summary reports. We describe and clarify these conditions in the following subsections.

FDA explained in the Final VMSR notice that individual reporting is necessary under certain circumstances for devices within product codes that are otherwise eligible for the VMSR Program. For certain individual reporting conditions, as described below, manufacturers are responsible for identifying whether the condition applies. For other individual reporting conditions, FDA will notify manufacturers that individual reporting is necessary. Such notifications will explain why FDA determined that individual reporting is necessary and, as appropriate, the steps necessary for a manufacturer to resume summary, quarterly reporting.

Manufacturers participating in the VMSR Program must submit individual reports in the following circumstances, in accordance with the conditions of the program:

(1) Reportable malfunction is associated with a 5-day report

Under 21 CFR 803.53(a), a manufacturer must submit a 5-day report if it becomes aware of an MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. After submitting a 5-day report required under 21 CFR 803.53(a), all subsequent reportable malfunctions of the same nature that involve substantially similar devices[21] must be submitted as individual MDRs pursuant to 21 CFR 803.50 and 803.52, unless FDA notifies the manufacturer that the issue has been resolved to FDA's satisfaction and individual reports are no longer required. Summary reporting of malfunctions may then resume on the regularly scheduled summary reporting cycle.[22] Submission of reportable malfunctions associated with 5-day reports in this manner will assist FDA in monitoring the time course and resolution of the issue presenting an unreasonable risk of substantial harm to the public health.

(2) A reportable malfunction is the subject of certain device recalls

As stated in section IV.B.2. of the Final VMSR notice (83 FR 40973[23]), when a device is the subject of a recall involving the correction or removal of the device to address a malfunction and that correction or removal is required to be reported to FDA under 21 CFR Part 806 (this includes class I and class II recalls, but not class III recalls),[24] all reportable malfunction events

[19] Available at https://www.federalregister.gov/d/2018-17770.

[20] Throughout this section, FDA uses the term "must" to describe conditions of the VMSR Program consistent with the Final VMSR Program notice as well as to describe statutory or regulatory requirements.

[21] For example, and consistent with the Final VMSR notice, a "substantially similar" device could be a device that is the same except for certain performance characteristics or a device that is the same except for certain cosmetic differences in color or shape. See Final VMSR notice, section II.C (83 FR 40973).

[22] Final VMSR notice, section IV.B (83 FR 40973).

[23] Available at https://www.federalregister.gov/d/2018-17770.

[24] See 21 CFR 7.3(m) for the definition of each numerical recall classification.

of the same nature[25] that involve the same device or a similar device marketed by the same manufacturer must be submitted as individual MDRs in accordance with 21 CFR 803.50 and 803.52 until the date that the recall is terminated by FDA.[26] After the recall is terminated, summary reporting may resume on the regularly scheduled summary reporting cycle, unless after the recall event, FDA has revoked the VMSR Program alternative with respect to that device product code.

The requirement to submit individual reports under this condition is triggered on the date that the manufacturer submits a report of a correction or removal required under 21 CFR Part 806 (or the date that the manufacturer submits a report of the correction or removal under 21 CFR part 803 or 21 CFR part 1004 instead, as permitted under 21 CFR 806.10(f)). This will allow FDA to monitor the frequency of reportable malfunctions associated with the recall and effectiveness of the recall strategy.

If a manufacturer becomes aware of reportable malfunction events before the date that the requirement to submit individual reports is triggered and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit any of those malfunction events related to the recall in a summary MDR format within 30 calendar days of submitting the required report of correction or removal. In the summary MDR, the manufacturer should include a check box of recall in section H.7 ("If Remedial Action Initiated, Check Type**"**) of the electronic Form FDA 3500A.

(3) FDA has determined that individual MDR reporting is necessary to address a public health issue

If FDA determines that individual malfunction reports are necessary to provide additional information and more rapid reporting for an identified public health issue involving certain devices, manufacturers must submit reportable malfunction events for those devices as individual MDRs pursuant to 21 CFR 803.50 and 803.52. Such determination may apply to all reportable malfunctions for a particular device or multiple devices (e.g., all devices within an eligible product code); such determination may also apply to only certain types of malfunctions for the particular device(s), depending on the scope of the public health issue.

As stated in the Final VMSR notice, FDA will provide written notification to manufacturers of relevant devices that individual MDR submissions are necessary. FDA will also provide further written notice when manufacturers of those devices may resume participation in summary malfunction reporting. If a manufacturer becomes aware of reportable malfunction events before receiving written notice to submit such events individually, and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit malfunction events for the identified devices to FDA within 30 calendar days of receiving notification from FDA.

[25] By "malfunction events of the same nature" and consistent with the Final VMSR notice, FDA means additional reportable malfunction events involving the same malfunction that prompted the recall.

[26] See 21 CFR 7.55 (describing when recalls will be terminated).

Below, we have provided examples of situations where FDA has determined that individual MDR reporting is necessary to address a public health issue, and summary reporting would not be appropriate. However, public health issues are not uniform, can be unpredictable, and may arise in various ways; the following are examples, and there may be other scenarios not described below where individual malfunction reports are necessary to address or evaluate a public health issue. As illustrated below, this individual reporting condition may apply to reporting for a particular device or multiple devices of the same type, or only to certain types of malfunctions for that device type.

Examples of Circumstances in which FDA has Determined Individual Malfunction Reporting is Necessary:

- Where FDA has determined that certain reusable devices that fall within eligible product codes may have a high risk of infection if they are not adequately reprocessed, which FDA considers a public health issue.
- Where there is an ongoing safety signal or other safety-related investigation of a known or potential public health concern.
- Where root causes of malfunction events are not well understood.

(4) FDA has determined that a device manufacturer may not report in summary reporting format

FDA may determine that a specific manufacturer may no longer participate in the VMSR Program for reasons including, but not limited to, failure to comply with applicable MDR requirements under 21 CFR Part 803, failure to follow the conditions of the VMSR Program, or the need to monitor a public health issue such as an investigation into safety-related issues at a specific manufacturer's establishment.[27]

As we stated in section IV.B.3 of the Final VMSR notice, in these cases, FDA will provide written notification to the device manufacturer to submit individual malfunction reports in compliance with 21 CFR 803.50 and 803.52. The requirement to submit individual reports under this condition is triggered on the date the manufacturer receives the written notification from FDA. If a manufacturer became aware of reportable malfunction events before the date that the requirement to submit individual reports is triggered under this condition and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit those malfunction events within 30 calendar days of receiving notification from FDA.[28]

(5) A new type of reportable malfunction occurs for a device

As stated in the Final VMSR notice, if a manufacturer becomes aware of information reasonably suggesting that a reportable malfunction event has occurred for a device that the manufacturer markets and the reportable malfunction is a new type of malfunction that the manufacturer has not previously reported to FDA for that device, then the manufacturer must submit an individual report for that reportable malfunction in compliance with 21 CFR 803.50 and 803.52. After the manufacturer submits this initial individual report, subsequent malfunctions of this type may be

[27] Final VMSR notice, section IV.B.4 (83 FR 40973).
[28] Final VMSR notice, section IV.B.4 (83 FR 40973).

submitted in summary form according to the quarterly reporting schedule described in Section V.C(2) of this guidance document, unless another individual reporting condition applies.

B. Supplemental Reports

Under the VMSR Program, in general, if a manufacturer becomes aware of information required in a malfunction summary report that the manufacturer did not submit to FDA because the information was not previously known or was not available when the manufacturer submitted the initial summary malfunction report, then the manufacturer must submit the supplemental information to FDA in an electronic format in accordance with 21 CFR 803.12(a). As set forth in the Final VMSR notice (83 FR 40973[29]), supplemental information must be submitted by manufacturers to FDA by the submission deadline described in Table 1—Summary Malfunction Reporting Schedule of the Final VMSR notice,[30] which we provide below in Section V.C(2) of this guidance document. Supplemental information must be submitted by the applicable deadline according to the date on which the manufacturer becomes aware of the supplemental information. Manufacturers must also continue to follow the requirements for the content of supplemental reports set forth in 21 CFR 803.56, meaning that for a supplemental or follow-up report, the manufacturer must:

a. Indicate that the report being submitted is a supplemental or follow-up report;
b. Submit the appropriate identification numbers of the report that is being updated with the supplemental information (i.e., original manufacturer report number on which the report was based); and
c. Include only the new, changed, or corrected information.

If a manufacturer submits a summary malfunction report and subsequently becomes aware of information reasonably suggesting that an event (or events) previously submitted in a malfunction summary report represents a reportable serious injury or death event, or a new type of reportable malfunction, the manufacturer must submit an initial, individual MDR for the identified serious injury, death, or new type of reportable malfunction event within 30 calendar days of becoming aware of the additional information. The manufacturer must also simultaneously submit a supplemental report to update the initial malfunction summary report and include only the new, changed, or corrected information.

C. Summary Reporting Instructions

To meet the conditions of the VMSR Program alternative granted under 21 CFR 803.19, manufacturers of devices in eligible product codes who elect to participate in the VMSR Program must submit summary malfunction reports in the format described under section IV.D, "Malfunction Reporting Summary Format" of the Final VMSR notice, completing the applicable sections of Form FDA 3500A,[31] which must be submitted electronically.

[29] Available at https://www.federalregister.gov/d/2018-17770.
[30] Final VMSR notice, section IV.F (83 FR 40973).
[31] Available at https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities.

FDA has included an example in Appendix A: Example of Malfunction Summary Reports of this guidance document.

(1) Instructions using Form FDA 3500A

Separate summary malfunction reports must be submitted for each unique combination of brand name, device model, and MDR adverse event code(s).[32,33] We note that manufacturers must include the device identifier (DI)[34] portion of the unique device identifier (UDI) in each Form FDA 3500A, if available. The summary reporting instructions are the same across devices and device-led combination products.

Each summary malfunction report must include at least the following information collected on Form FDA 3500A and must be submitted in electronic format. This information should be placed in the corresponding field of the form, as described in the form's instructions.

- **Describe Event or Problem** – The device event narrative must include a detailed description of the nature of the events and, if relevant and available, we recommend including a range of patient age and weight and a breakdown of patient gender, race, and ethnicity. Inclusion of patient age, weight, gender, race, and ethnicity is not a required entry for the form; however, FDA recommends including these descriptors in a text narrative if the information is available and indicates that a malfunction is more likely to affect a specific group of patients.[35]
- **Brand Name** – Include the device brand name.
- **Common Device Name and Product Code** – Include the common name of the device and its product code.
- **Manufacturer Name, City, and State** – Add the manufacturer's name and identify its location. Multiple manufacturing sites could be entered in the form if the device is manufactured at multiple sites.[36]
- **Model Number and other device identifying information** – Enter the device model and/or catalog number and lot number(s) and/or serial number(s) for the devices that are the subject of the MDR. Include any DI portion of the UDI[37] for the device version or model that is the subject of the MDR. If more than one DI is associated with the summary report and the Device Identification field cannot accommodate all associated DI information, the additional narrative field may be used to identify all associated DIs, in addition to the other manufacturer narrative information.
- **Contact Office (and Manufacturing Site(s) for Devices)** – Enter the name, address, and email of the manufacturer reporting site (contact office), including the contact

[32] Information on MDR Adverse Event Codes can be found at https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/mdr-adverse-event-codes

[33] Final VMSR notice, section IV.D (83 FR 40973).

[34] The device identifier is a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. 21 CFR 803.3.

[35] See Final VMSR notice (83 FR 40973).

[36] Final VMSR notice (83 FR 40973).

[37] For class I devices, the universal product code (UPC) may serve as the UDI (21 CFR 801.40(d)). In these instances, include the UPC in Section D.4.

name for the summary report being submitted. Enter the name and address of the manufacturing site(s) for the device, if different from the contact office.

- **Phone Number of Contact Office** – Add a phone number for the contact office.
- **Combination Products** (if applicable) –Check if the report involves a combination product. Manufacturers may also enter other applicable information.
- **Type of Reportable Event** – Check "Malfunction". Manufacturers may check "Summary Report" boxes and identify the number of events.
- **Adverse Event Problem** – Enter the corresponding codes, including as many codes as necessary to describe the event problem and evaluation for the reportable malfunction events that are being summarized:
  - Medical Device Problem Code
  - Type of Investigation
  - Investigation Findings
  - Investigation Conclusions, even if the device was not evaluated
- **Additional Manufacturer Narrative** – Provide a summary of the results of the investigation for the reported malfunctions, including any follow up actions taken, and any additional information that would be helpful in understanding how the manufacturer addressed the malfunction events summarized in the report. Enter a breakdown of the malfunction events summarized in the report: the number of devices that were returned, the number of devices that were labeled "for single use" (if any), and the number of devices that were reprocessed and reused (if any).

(2) Reporting Schedule and Logistics

As stated in section IV.F of the Final VMSR notice (83 FR 40973[38]), to meet the conditions of the alternative established under the VMSR Program, manufacturers submitting malfunction summary reports or supplemental reports to a malfunction summary report must submit those reports electronically[39] on a quarterly basis according to the schedule in Table 1. The summary malfunction report must include the MDR Number, which consists of the registration number of the manufacturer, the year in which the event is being reported, and a 5-digit sequence number. Information included in a malfunction summary report must be current as of the last date of the quarterly timeframe identified in Table 1.

All reportable malfunction events for eligible product codes may be reported in the summary format described in Section V.C(1) of this guidance, unless the events are excluded from the scope of the VMSR Program or subject to one of the individual reporting conditions of the program (see Sections IV.B-**0**). If a manufacturer elects to participate in the VMSR Program, the summary reports must be submitted to the FDA on a quarterly basis, according to Table 1.

Table 1. VMSR Reporting Schedule

[38] Available at https://www.federalregister.gov/d/2018-17770.

[39] For more information, see the FDA guidance "Questions and Answers about eMDR - Electronic Medical Device Reporting," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/questions-and-answers-about-emdr-electronic-medical-device-reporting-guidance-industry-user.

Reportable malfunctions that a manufacturer become aware of during these timeframes	**Should be submitted to the FDA by**
January 1 – March 31	April 30
April 1 – June 30	July 31
July 1 – September 30	October 31
October 1 – December 31	January 31

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Appendix A: Example of Malfunction Summary Reports

The following hypothetical example is solely meant to illustrate how to summarize malfunction events in summary reports under the VMSR Program. Real-world reporting scenarios will depend on the particular details of the malfunction(s) in question. Please note that Form FDA 3500A is subject to change over time, and the example provided below is solely meant to illustrate how the form might be filled out in the scenario described.

Multiple malfunction events with two device problems

A manufacturer receives 50 malfunction reports within the quarterly timeframe that include two types of device malfunctions that are related to a specific model (XYZ, Version 2, multiple UDI-DIs) of their AC powered ABC Bed: (1) 35 events involve a tear in a disposable cover; and (2) 25 events involve a screw that attaches the bed rail to the mounting bracket on the bed, which loosens due to vibration. Ten of the events involve both types of device malfunctions. None of the events involves patients. None of the events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

As stated in Section V.C., separate summary malfunction reports must be submitted for each unique combination of brand name, device model, and MDR adverse event code(s). In this example, there is one brand of device and one device model. There are three different combinations of adverse event codes, and therefore, three summary reports should be submitted to FDA:

1. Report #1: 25 events that involve torn covers only;
2. Report #2: 15 events that involve loose screws only; and
3. Report #3: 10 events that involve both torn covers and loose screws.

Manufacturers should note that the summary reporting format requires firms to identify the method, result, and conclusion codes in Form FDA 3500A, including as many codes as are necessary to describe the event problem and evaluation for the reportable malfunction events that are being summarized. If the report summarizes reportable events that involved more than one type of device problem, such as the example Report #3 described above, differences in the conclusion code according to the different device problems can be explained in the narrative text.[40]

[40] Final VMSR notice (83 FR 40973).