



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA-2017-N-6730]

Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; order granting alternative.

SUMMARY: The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are announcing that the Agency is granting an alternative that permits manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form on a quarterly basis. We refer to this alternative as the "Voluntary Malfunction Summary Reporting Program." This voluntary program reflects goals for streamlining malfunction reporting outlined in the commitment letter agreed to by FDA and industry and submitted to Congress, as referenced in the Medical Device User Fee Amendments of 2017 (MDUFA IV Commitment Letter).

DATES: This voluntary program applies only to reportable malfunction events that manufacturers become aware of on or after [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See further discussion in section IV.F. "Submission Schedule and Logistics."

FOR FURTHER INFORMATION CONTACT: Michelle Rios, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave.,

Bldg. 66, Rm. 3222, Silver Spring, MD 20993, 301-796-6107, MDRPolicy@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911; or CBER, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or by calling 1-800-835-4709 or 240-402-8010; or email: ocod@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Every year, FDA receives hundreds of thousands of MDRs of suspected device-associated deaths, serious injuries, and malfunctions. The Agency's MDR program is one of the postmarket surveillance tools FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Malfunction reports represent a substantial fraction of the MDRs FDA receives on an annual basis.

Medical device reporting requirements for manufacturers are set forth in section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) and the regulations contained in part 803 (21 CFR part 803). Among other things, part 803 requires the submission of an individual MDR when a manufacturer 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 (§§ 803.10(c)(1) and 803.50(a)(2)). Throughout this document, we refer to such malfunctions as “reportable malfunctions” or “reportable malfunction events.”

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) 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 those devices must continue to submit malfunction reports in accordance with part 803 (or successor regulations), unless FDA grants an exemption or variance from, or an alternative to, a requirement under such regulations under § 803.19. However, FDAAA amended the FD&C Act to require that malfunction 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--be submitted in accordance with the criteria established by FDA. The criteria require the malfunction reports to be in summary form and made on a quarterly basis (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. Under § 803.19, FDA may grant exemptions or variances from, or alternatives to, any or all of the reporting requirements in part 803, and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time

period. FDA may grant such modifications upon request or at its discretion, and when granting such modifications, FDA may impose other reporting requirements to ensure the protection of the public health. (See § 803.19(c))

In the *Federal Register* of December 26, 2017 (82 FR 60922), FDA issued a notification outlining FDA's proposal to grant an alternative under § 803.19 to permit manufacturer reporting of certain device malfunctions in summary form on a quarterly basis, subject to certain conditions, and requested comments (2017 Proposal). As explained in the 2017 Proposal, the Voluntary Malfunction Summary Reporting Program is intended to reflect goals for streamlining malfunction reporting that FDA and industry agreed to in the MDUFA IV Commitment Letter (Ref. 1). The 2017 Proposal also summarized FDA's previous experience with summary reporting programs, key findings from an FDA pilot program for the submission of MDRs in summary format on a quarterly basis (see 80 FR 50010, August 18, 2015), additional background regarding the development of the proposal, and the anticipated benefits of summary reporting under the proposal. Interested persons were given the opportunity to submit comments by February 26, 2018.

II. Comments on the Proposed Alternative and FDA's Response

In response to the 2017 Proposal, FDA received 24 comments from industry, professional societies, trade organizations, and individual consumers by the close of the comment period, each containing one or more comments on one or more issues. A summary of the comments to the docket and our responses follow. To make it easier to identify comments and our responses, the word "Comment" appears in parentheses before the comment's description, and the word "Response" in parentheses precedes the response. The comments are grouped based on common themes and numbered sequentially.

A. *General Comments.*

(Comment 1) Three comments suggested that the proposal was inconsistent with amendments made by section 227 of FDAAA to section 519(a) of the FD&C Act regarding malfunction reporting requirements. Two of these comments specifically recommended that FDA immediately implement summary, quarterly malfunction reporting under section 519(a)(1)(B)(ii) of the FD&C Act for all class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining.

(Response 1) FDA disagrees with these comments. As discussed in the 2017 Proposal, currently, there are still reportable malfunctions for which submission of individual malfunction reports on a prompter basis than quarterly is necessary to protect the public health--for example, when remedial action is needed to prevent an unreasonable risk of substantial harm to the public health. Those situations may involve class I devices and class II devices that are not permanently implantable, life supporting, or life sustaining, and it is not feasible for FDA to provide notice in the *Federal Register* or by letter to individual manufacturers, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act, each time one of these situations arises. For example, FDA may not become aware of the situation until it receives an MDR from a manufacturer. Therefore, in accordance with section 519(a)(1)(B)(i)(III) of the FD&C Act, manufacturers of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining remain subject to individual reporting requirements in part 803, unless granted an exemption, variance, or alternative, to protect the public health. However, FDA does believe that malfunction summary reporting on a quarterly basis, in accordance with the conditions described in section IV, will reduce burden on FDA and manufacturers and allow FDA to effectively monitor many devices. Accordingly, the Agency is granting an alternative

under section 519(a)(1)(B)(i) of the FD&C Act and § 803.19 to permit manufacturers of those devices to submit summary, quarterly malfunction reports, with certain conditions.

(Comment 2) Several comments raised concerns that the proposed program would be unable to provide FDA with critical information on adverse event reporting. Many of the comments from individual consumers also raised concerns that the proposed program would limit transparency of malfunction event data that is publicly available to patients and physicians, including transparency regarding the number of reported malfunctions. However, another comment indicated that the proposed program would minimize burden while maintaining patient safety. That same comment further indicated that the proposed malfunction summary reporting format would enhance public visibility into the events and associated investigation compared to a format previously used for the Alternative Summary Reporting (ASR) program.

(Response 2) FDA disagrees with the comments suggesting that the Voluntary Malfunction Summary Reporting Program will negatively affect patient safety and the transparency of malfunction reports. Summary, quarterly reporting in accordance with this program will result in some malfunction reports being submitted to FDA and added to the publicly available Manufacturer and User Facility Device Experience (MAUDE) database later than this occurs under FDA's current individual reporting requirements. However, as explained in our 2017 Proposal, we believe this reporting format and schedule will also yield benefits for FDA and the public, such as helping FDA process malfunction reports more efficiently and helping both FDA and the public more readily identify malfunction trends.

While summary malfunction reports submitted under this program will change the format in which information is presented to FDA, we do not believe there will be an adverse impact on the content of information provided to FDA. The format for summary reporting described in

section IV.D includes a narrative section for describing malfunctions, similar to the narrative section required for individual reporting. In addition, each narrative section is required to include a sentence specifying the number of malfunction events summarized in the report, providing transparency for the public regarding the number of events that a summary report available in MAUDE represents. Therefore, we agree with the comment that the summary reporting format will improve transparency for the public when compared to some past summary reports submitted to FDA, such as reports submitted under the ASR program (Ref. 2).

(Comment 3) One comment requested clarification as to whether a manufacturer would need to apply or obtain permission to participate in the program and asked FDA to clarify how the proposed program would work with other alternative summary reporting situations. Another comment asked FDA to clarify whether manufacturers can still apply for an exemption or variance to be granted under § 803.19 for their devices that do not fall under an eligible product code.

(Response 3) FDA is clarifying in the description of the alternative that manufacturers do not need to submit a request or application to FDA before participating in the Voluntary Malfunction Summary Reporting Program. For devices that fall within eligible product codes, the alternative that FDA is granting under § 803.19 provides that manufacturers may choose or “self-elect” to participate, subject to the program conditions identified in section IV. If a manufacturer wishes to request a different exemption, variance, or alternative under § 803.19 (including for devices in product codes that are eligible for the Voluntary Malfunction Summary Reporting Program) the manufacturer may submit a request to FDA. For more information regarding the recommended content of such requests, see section 2.27 of the Agency’s guidance

entitled “Medical Device Reporting for Manufacturers: Guidance for Industry and Food and Drug Administration Staff” (MDR Guidance) (Ref. 3).

Whether participation in the Voluntary Malfunction Summary Reporting Program will have an impact on a manufacturer being granted a different exemption, variance, or alternative under § 803.19 will depend on the scope of the other exemption, variance, or alternative. FDA will make a case-by-case determination on requests for an exemption, variance, or alternative submitted under § 803.19(b).

B. Scope of Program

(Comment 4) Several comments also discussed the scope of product codes that should be eligible for the proposed program. One comment expressed concern about including class III devices and class II devices that are permanently implantable, life-supporting, or life-sustaining in the program and urged FDA to issue another *Federal Register* notice with the list of eligible product codes for these categories of devices for public comment before allowing summary, quarterly malfunction reporting for those devices. In contrast, another comment asserted that all devices should be eligible for malfunction summary reporting, unless there is an express determination, subject to public input, that permitting summary reporting for a device would present public health concerns. Other comments recommended that all device product codes should be eligible for summary, quarterly malfunction reporting, with the exception of product codes for class III devices and class II devices that are permanently implantable, life supporting, or life sustaining when those product codes have been in existence for less than 2 years.

(Response 4) FDA disagrees that it should publish another *Federal Register* notice for public comment listing product codes that would be eligible or ineligible for the program. Among other reasons, the Agency expressly requested comment on the product codes that should be eligible for the proposed program, and many commenters submitted proposed lists of eligible

product codes or identified specific devices about which they had concerns. FDA has considered these comments and has also conducted an extensive review of all product codes, regardless of device class, to determine whether each product code would be eligible. In addition, consistent with its 2017 Proposal, product codes that have been in existence for less than 2 years are not included in the list of eligible product codes, unless the new product code was created solely for administrative reasons. In FDA's experience, this 2-year period is an important period for having more timely, detailed information to monitor malfunction events. That 2-year timeframe for new product codes is also consistent with the MDUFA IV Commitment Letter (Ref. 1).

(Comment 5) Three comments recommended that importers be included within the scope of the proposed program and indicated that FDA should provide a rationale for not including them. One of those comments suggested that without more information, it appeared arbitrary that FDA did not include importers and user facilities in the summary reporting program.

(Response 5) FDA disagrees with these comments. Unlike manufacturers, device user facilities are not required to submit malfunction reports under part 803. User facilities, such as hospitals or nursing homes, are required to submit MDRs to FDA and/or the manufacturer *only* for reportable death or serious injury events. (See section 519(b) of the FD&C Act; § 803.30(a))

Importers are also subject to different requirements for reporting device malfunctions than those for manufacturers under part 803. Under § 803.40, importers are required to submit a report to the device manufacturer, not to FDA, within 30 days after becoming aware of a reportable malfunction event. Manufacturers then determine the reportability of the information received from the importer and accordingly submit those reports to FDA. This program specifically addresses malfunction summary reporting to FDA. In addition, we believe it is important for importers to continue to submit individual malfunction MDRs to device

manufacturers in accordance with § 803.40 so that manufacturers receive detailed information necessary to conduct adequate investigations and follow up related to malfunction events.

C. Individual Reporting Conditions

(Comment 6) One comment suggested that when requesting that a manufacturer submit a 5-day report, FDA should have an objective and documented basis for making such a request, as well as an opportunity for manufacturers to appeal. Other comments asked FDA to define the term “substantially similar” as used in describing the program condition regarding 5-day reports and to clarify what constitutes an “imminent hazard” and whether this is analogous to reportable malfunctions requiring a 5-day report.

(Response 6) The circumstances in which a 5-day report is required are defined under § 803.53, and those circumstances remain unchanged for manufacturers participating in the Voluntary Malfunction Summary Reporting Program. As stated in the 2017 Proposal, the reporting requirements at § 803.53 will continue to apply to manufacturers of devices in eligible product codes who participate in this program. We have added a separate heading to the description of the alternative to clarify this point further. For more information regarding the handling of a 5-day report, please see section 2.20 of the Agency’s MDR Guidance (Ref. 3).

The first individual reporting condition requires that if a manufacturer submits a 5-day report for an event or events that require remedial action to prevent an unreasonable risk of substantial harm to public health, all subsequent reportable malfunctions of the same nature that involve substantially similar devices must be submitted as individual MDRs in accordance with §§ 803.50 and 803.52 until the date that the remedial action has been resolved to FDA’s satisfaction. For purposes of this individual reporting condition, a “substantially similar” device

could be, for example, 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.

Regarding the term “imminent hazard,” FDA notes that the term is used to describe one of the general overarching principles for summary reporting, but is not included in the descriptions of any of the individual reporting conditions. For purposes of these overarching principles, we intend “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. Use of that term in one of the overarching principles was not intended to indicate any change in the standard for a 5-day report under § 803.53.

(Comment 7) One comment indicated that there should be objective and documented criteria for when FDA would provide written notice that manufacturers must submit an individual, 30-day malfunction report in accordance with the proposed program conditions, along with an opportunity for appeal. The comment further asserted that due process considerations need to be made regarding these reporting requirements, including notice, a written justification for the request, and a process to appeal.

(Response 7) FDA disagrees that there should be fixed criteria for notifying a manufacturer that it must submit an individual, 30-day malfunction report in accordance with the program conditions. Manufacturers who are notified to submit individual reports in accordance with the individual reporting conditions will need to comply with MDR requirements to which they would otherwise be subject if not granted this alternative under § 803.19. FDA has provided examples of when it would make these notifications, but public health issues that require submission of individual MDRs to monitor device safety are not uniform and may arise in various ways.

FDA will provide written notice to manufacturers when they need to submit individual MDRs pursuant to individual reporting conditions 3 and 4, as described in section IV.B. In addition, the Agency already has a process in place for stakeholders to request review of decisions made by CDRH employees. For more information, refer to the FDA Guidance entitled “Center for Devices and Radiological Health Appeals Processes” (Ref. 4).

(Comment 8) Some comments disagreed with the proposed program condition that would have required manufacturers to submit individual, 30-day MDRs for reportable malfunction events that are the subject of any ongoing device recall and suggested that the condition be modified or removed. The comments cited several different reasons for objecting to this condition, including that the condition is not mentioned in the MDUFA IV Commitment Letter, that the condition may discourage manufacturers from conducting voluntary or class III recalls, that the condition is duplicative of information that FDA receives during a recall, and that it may be difficult for manufacturers to manage the requirements (e.g., new events may be uncovered during a product investigation leading to confusion and multiple reports for the same incident). Suggestions from the commenters regarding this individual reporting condition included the following: (a) the condition should only apply to mandatory or FDA-initiated recalls, and summary reporting should be permitted for voluntary or low-risk class III recalls and for incidents related to remedial action after the first (parent) MDR is submitted, unless a death or serious injury is associated; (b) FDA should clarify how to handle malfunction events that were not submitted as individual MDRs, but subsequently, prior to the next summary reporting date, are identified to be the result of an issue addressed by a recall; (c) the timeframe for submitting individual MDRs should be changed from 90 days past the date of the termination of the recall

to 90 days past the date of the recall; and (d) FDA should clarify what it means by “malfunction events of the same nature.”

(Response 8) FDA disagrees with the comments recommending removal of this individual reporting condition. Recall classification takes into account both the severity of harm and the likelihood of occurrence, and it is important for FDA to have access to more timely information on malfunctions related to certain recalls to ensure that the recall has been appropriately classified and that the recall strategy is effective.

FDA also provides the following responses to the additional specific issues raised in the comments: (a) for the reasons discussed above, FDA continues to believe that it is important for malfunctions related to certain recalls to be reported as individual MDRs. However, after considering the comments, FDA has determined that this individual reporting condition should only apply to reportable malfunctions that are the subject of a recall involving a correction or removal that must be reported to FDA under part 806 (21 CFR part 806). Under part 806, manufacturers and importers are required to make a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, unless the information has already been submitted to FDA in accordance with other reporting requirements. (See § 806.10(a) and (f).) Because the definition of “risk to health” under part 806 tracks the definitions of class I and class II recalls in § 7.3(m) (21 CFR 7.3(m)), reports of corrections and removals are required for actions that meet the definition of class I and class II recalls. However, under part 806, manufacturers and importers need not report events that are categorized as class III recalls under § 7.3(m) (see 62 FR 27183, May 19, 1997). Therefore, an action that meets the definition of a class III recall would not, on its own,

trigger the requirement to submit individual reports under the Voluntary Malfunction Summary Reporting Program.

(b) FDA agrees that it is important to provide clarity regarding when the requirement to submit individual MDRs is triggered under this individual reporting condition and the events to which that requirement applies. Therefore, FDA is revising the alternative to clarify that, as of the date a manufacturer submits a required report of a correction or removal under part 806 (or the date that the manufacturer submits a report of the correction or removal under 21 CFR part 803 or part 1004 instead, as permitted under § 806.10(f)), the manufacturer must submit reportable malfunction events related to that correction or removal as individual MDRs in accordance with §§ 803.50 and 803.52. We believe these revisions will help provide manufacturers with a clear date on which this individual reporting obligation is triggered.

With respect to malfunction events that were identified for inclusion in a summary report but are subsequently identified as the subject of a reportable correction or removal prior to the end of the relevant summary reporting period, FDA is revising the alternative to state that a summary MDR must be submitted for those reportable malfunctions within 30 calendar days of when the manufacturer submits the required report of correction or removal. In the summary report, the manufacturer must include a check on the box for “Recall” in SECTION H.7 of the electronic Form FDA 3500A. We have similarly revised the description of individual reporting conditions 3 and 4 to clarify the requirements for handling malfunction events identified for inclusion in a summary report (but not yet submitted) prior to the date that individual reporting is triggered.

(c) As part of its recall termination process, FDA considers MDR information, including reported malfunctions to help evaluate the effectiveness of the recall. Therefore, FDA disagrees

with the suggestion to limit the duration of individual reporting under this condition to 90 days past the date of a recall. However, after considering the comments, we do not believe it is necessary to receive individual MDRs for reportable malfunction events that are the subject of a recall after FDA has terminated the recall. We have revised the alternative accordingly (see Section IV.B.2.). For similar reasons, we have revised the first individual reporting condition to state that individual MDRs associated with a 5-day report are only required until the remedial action at issue is resolved to FDA's satisfaction.

(d) By "malfunction events of the same nature," FDA means additional reportable malfunction events involving the same malfunction that prompted the recall.

(Comment 9) One comment, regarding proposed individual reporting condition 3, suggested that FDA provide information on the timing for when the Agency will provide written notice to a manufacturer that the manufacturer can resume participation in the Voluntary Malfunction Summary Reporting Program.

(Response 9) FDA cannot provide a uniform timeframe for when the Agency would notify manufacturers submitting individual reports due to an identified public health issue that they can resume submission of summary, quarterly malfunction reports for those devices because the timing and resolution of public health issues is specific to each situation.

(Comment 10) Three comments recommended that FDA clarify what constitutes a "new type of reportable malfunction" that is exempt from summary reporting. One of these comments indicated that FDA should provide additional information regarding when a manufacturer can begin submitting summary reports for these new types of device malfunctions.

(Response 10) FDA disagrees that the meaning of the phrase "new type of reportable malfunction" was unclear in the proposal. Manufacturers are required under § 820.198 (21 CFR

820.198) to evaluate complaints to determine if they represent events that must be reported to FDA under part 803 or if an investigation is required. Through this process, if a manufacturer identifies a new type of reportable malfunction that has not previously been reported to FDA over the life of that device, this information must be submitted to FDA as an individual MDR in accordance with §§ 803.50 and 803.52 and may not be reported to FDA in a summary malfunction report. This will allow FDA and manufacturers to better understand and address emergent issues with medical devices. We have revised this individual reporting condition to clarify that after manufacturers submit an individual MDR for the initial occurrence of a previously unreported type of reportable malfunction for a device, subsequent reports for that same type of malfunction for that device may be in summary form, unless they are subject to individual reporting for another reason.

D. Reporting Format

(Comment 11) Some comments suggested that FDA allow manufacturers to "bundle together" reportable malfunction events in a summary report by product code or product family and allow the use of International Medical Device Regulators Forum's (IMDRF) Level 1,2 codes to bundle like events in a summary report.

(Response 11) FDA disagrees with the suggestion that manufacturers be permitted to bundle reportable malfunction events by product code or product family for purposes of submitting a summary report. Each unique combination of device brand name (corresponding to SECTION D1 of the Form FDA 3500A), device model, and device problem code(s) (corresponding to SECTION F10/H6 of the Form FDA 3500A) can be summarized together in reports submitted under this program. (Comments regarding the number of brand names that should be included in each summary report are further addressed in the response to Comment 16

below, and we have made corrections to the summary reporting instructions for SECTION D.4 to be clear that each summary malfunction report should summarize events for a single device model.) Bundling together malfunction reports by product codes or device families would make summarizing and interpreting the information in a summary report difficult for manufacturers, FDA, and the public because a product code or product family could contain several devices with different functions, components, and modes of operation that are important for purposes of understanding malfunction events and the causes of those events. The intent of the Voluntary Malfunction Summary Reporting Program is to streamline reporting of events that are the same or similar, yet not to over bundle reports such that important details regarding device performance are obscured.

The IMDRF (Ref. 5) is working towards harmonization of all medical device coding, including device problem codes. To harmonize medical device coding globally, device problem codes have been organized in a hierarchical arrangement, such that higher level codes (e.g., electrical issue) describe more general device problems, while lower level codes (e.g., insulation issue) provide more granularity into the type of device problem described. For purposes of grouping device issues for reports submitted under this Voluntary Malfunction Summary Reporting Program, we recommend that all coding be grouped at the lowest level of coding available, when IMDRF codes are available. Based on our experience, FDA does not believe grouping by the lowest level of coding will eliminate the efficiency benefits of summary reporting. FDA does not specify a specific level of coding, but expects the most specific appropriate code to be used.

(Comment 12) One comment noted that it was unclear whether a summary malfunction report will be available in MAUDE or another database. Another comment recommended that FDA allow Excel spreadsheets with malfunction report data to be uploaded to MAUDE.

(Response 12) FDA plans to make summary reports submitted under the Voluntary Malfunction Summary Reporting Program publicly available in MAUDE. However, FDA will not upload Excel spreadsheets to MAUDE because they are incompatible with the MAUDE interface.

(Comment 13) One comment indicated that FDA should consider amending the requirement that an individual process the complaints twice--once for reporting assessment and then quarterly.

(Response 13) FDA disagrees with this comment. FDA is granting an alternative to the individual reporting requirements under part 803 for certain reportable malfunction events. The Quality System (QS) regulation requires manufacturers to evaluate all complaints to determine if they represent events that must be reported to FDA under part 803 (§ 820.198(a)). If a complaint represents an MDR reportable event, then the manufacturer must, among other things, investigate it and submit an MDR to FDA. (See §§ 803.10(c), 803.50, and 820.198(d)) The difference for manufacturers that have been granted the alternative described in this document is that they could choose to report certain malfunction events to FDA as a summary report instead of as an individual report.

(Comment 14) One comment requested that FDA provide more detail concerning the terms “similar device” and “similar complaint,” as used in the discussion of the rationale for the proposed summary reporting format.

(Response 14) The term “similar device” is used in FDA’s MDR regulations to describe malfunction events for which manufacturers must submit a report to FDA. (see e.g., § 803.50(a)(2)) As used in this alternative, the term “similar device” is intended to have the same meaning as it does for purposes of part 803. FDA’s MDR Guidance (Ref. 3), provides more information regarding the factors that FDA and manufacturers may consider in determining if a device is “similar” to another device.

FDA does not believe it is necessary to provide a formal definition of the term “similar complaint” for purposes of this alternative because that term is not used in describing any of the conditions of the Voluntary Malfunction Summary Reporting Program, including the required reporting format. Whether a complaint constitutes a “similar complaint” for purposes of conducting an investigation under FDA’s QS regulation is outside the scope of this alternative.

(Comment 15) One comment asked FDA to provide further information on how a manufacturer is to provide supplemental information, including whether FDA expects such information to be shared with the Agency. Some comments also noted that FDA should explain how a previously submitted summary malfunction report should be updated with new information, including how to handle new information regarding a previously reported event that would change the categorization of the event (e.g., if the manufacturer subsequently became aware that a serious injury was associated with a previously reported malfunction event).

(Response 15) FDA understands the need for clarification of how to handle additional information and supplemental reporting under this program and has revised the alternative to address this issue. A manufacturer participating in the Voluntary Malfunction Summary Reporting Program must submit an initial summary report within the Summary Malfunction Reporting Schedule timeframe described in table 1. Supplemental reports to a summary

malfunction report must also be submitted within that timeframe. For example, if a manufacturer submits a summary report for certain malfunction events of which it became aware in January to March and in May of that same year becomes aware of additional information that would have been required in the initial summary report if it had been known to the manufacturer, then the manufacturer must submit a supplemental report with that additional information by July 31. Manufacturers do not need to submit a supplemental report for new information if they would not have been required to report that information had it been known or available at the time of filing the initial summary malfunction report.

However, this timing for supplemental reports would not apply when additional information is learned about an event or events included in a previously submitted summary report that triggers individual reporting requirements. For example, if the manufacturer becomes aware of additional information reasonably suggesting that a previously reported malfunction meets the criteria for a reportable serious injury or death event, then the manufacturer must submit an initial, individual MDR for the identified serious injury or death within 30 calendar days of becoming aware of the additional information. The manufacturer must simultaneously submit a supplement to the initial MDR summary report reducing the number of events summarized by 1, so that the total number of events remains the same. The alternative has been revised to reflect that these are requirements for participating in the Voluntary Malfunction Summary Reporting Program.

(Comment 16) One comment stated that Form FDA 3500A is not an optimal format because it is only used for single event reporting. Other comments made specific recommendations and/or raised issues regarding the proposed summary reporting format using Form FDA 3500A, including the following: (a) in Form FDA 3500A, SECTIONS B.5 and H.10,

FDA should request that information be entered in a summary, high-level form, rather than requiring detailed descriptions or itemized investigation findings; (b) clarify the most “up to date” information that is expected to be received in the report; (c) clarify that only one brand name per product code should be entered in the field with additional brand names being provided in a separate attachment (SECTION D.1); (d) inclusion of patient age, weight, and breakdown of gender and race is inappropriate for summary malfunction reporting, and it is not clear if such information is required in a summary malfunction report; (e) clarify that manufacturers can submit summary malfunction reports for devices manufactured at multiple manufacturing sites (SECTION D.3); (f) the summary format should permit a serial number to be used instead of a lot number to identify the devices that are the subject of a summary report (SECTION D.4); and (g) address how a manufacturer should link a device problem code with a method code, result code, and evaluation conclusion code (if different) for a single summary report that includes more than one device problem.

(Response 16) FDA does not believe the summary reporting format should be changed to use a new form. The Voluntary Malfunction Summary Reporting Program aims to, among other things, consolidate reporting of same or similar events into a single summary report to reduce the overall volume of reports, while still providing critical content to FDA. While the Form FDA 3500A was developed for individual MDRs, manufacturers successfully used the Form FDA 3500A to submit summary malfunction reports in FDA’s pilot program. In addition, as explained in our 2017 Proposal, for purposes of streamlining changes that FDA and manufacturers must make to process or submit summary reports under the Voluntary Malfunction Summary Reporting Program, we believe that using the Form FDA 3500A is the most efficient approach. We provide the following responses to the specific

recommendations/issues raised regarding the summary reporting format: (a) FDA continues to believe that it is important for summary malfunction reports submitted under this program to provide a similar level of detail in text narratives as is available in an individual report to allow for sufficient understanding of the malfunction, any circumstances that led to the malfunction, and any follow-up steps the manufacturer has taken to investigate, correct, and prevent the malfunction from happening again. These narrative text fields are key to helping ensure that summary reporting under this program streamlines malfunction reporting without reducing the reporting of important details regarding device performance and transparency to the public. (b) Each summary report must be “up to date,” meaning that it must include all required information available, as of the close of the quarterly time period listed in the Summary Malfunction Reporting Schedule (see table 1). FDA has clarified this in section IV.F. (c) FDA disagrees that separate attachments with additional brand names should be permitted to accompany a summary malfunction report. Each summary malfunction report may only summarize malfunction events for a single brand name. We further clarified this in the instructions for the summary reporting format at section IV.D. Including multiple brand names in an attachment to a single summary report would, among other things, result in FDA having difficulty identifying the specific malfunction event to the exact device brand. (d) FDA agrees that information summarizing patient age, weight, gender, race, and ethnicity may not be relevant for many summary malfunction reports. FDA is revising the description of the summary reporting format to clarify that inclusion of this information in Section B.5 is not a required entry for the form. However, FDA recommends including descriptors such as patient weight or race in a text narrative for a malfunction summary report if the information is available and indicates that a malfunction is more likely to affect a specific group of patients. (e) FDA is revising the description of the

summary reporting format to clarify that multiple manufacturing sites could be entered in SECTION G.1 if the device is manufactured at multiple sites. We note that depending on their roles, each manufacturing site may be responsible for submitting MDRs. (See e.g., section 2.17 of FDA's MDR Guidance (Ref. 3), which provides additional information regarding reporting obligations for contract manufacturers.) (f) FDA agrees that a serial number may be included in SECTION D.4 and has added "serial number" to the reporting format instructions for that section. (g) The summary reporting format requires firms to identify the method, result, and conclusion codes in Block H6 of the 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 (see e.g., Case Scenario #2, Report #3 in Appendix A (Ref. 6)), differences in the conclusion code according to the different device problems can be explained in SECTION H.10.

E. Consideration of Combination Products

(Comment 17) Some comments raised issues regarding the application of the malfunction summary reporting for combination products that contain a device constituent part but that are marketed under drug or biological product marketing authorization pathways (referred to in this document as drug and biologic-led combination products), as opposed to those under device marketing authorization pathways (device-led combination products). Issues raised in these comments include: concerns about a device product code-based eligibility approach for drug and biologic-led combination products because such products may not have a device product code; the quarterly schedule proposed because it would create redundancies for drug and biologic-led combination products, which are subject to periodic reporting; the format proposed because it

might not be compatible with the reporting systems for drugs or biological products that are utilized for drug and biologic-led combination products; and development of a single report that includes malfunction summary reporting and satisfies other combination product reporting requirements.

(Response 17) Among other things, the final rule on postmarketing safety reporting (PMSR) for combination products (81 FR 92603, December 20, 2016), codified in part 4, subpart B (21 CFR part 4, subpart B), clarified that all combination product applicants must comply with malfunction reporting requirements as described in part 803 if their combination product contains a device constituent part. Accordingly, in the 2017 Proposal, FDA requested comment on how the Voluntary Malfunction Summary Reporting Program might be implemented for combination products, including drug and biologic-led combination products. Shortly after the issuance of the proposal for this program, FDA also published a draft guidance entitled, “Postmarketing Safety Reporting for Combination Products; Guidance for Industry and FDA Staff” (PMSR draft guidance) (Ref. 7) regarding compliance with the final rule on PMSR for combination products, and an Immediately in Effect guidance announcing FDA’s compliance policy for that rule (Ref. 8). The PMSR draft guidance noted that the Agency was proposing the Voluntary Malfunction Summary Reporting Program and stated that the Agency intends to update the PMSR draft guidance if combination products are included in the program. The compliance policy guidance announced the Agency’s intent to delay enforcement of certain provisions of the rule, including malfunction reporting requirements for drug and biologic-led combination products, to provide applicants with additional time to consider Agency recommendations and technical specifications as they update their systems and procedures to comply with those provisions.

Applicants of device-led combination products must submit MDRs in accordance with part 803 (see § 4.104 (21 CFR 4.104)), and therefore, they report malfunctions using the same system as device manufacturers. Thus, FDA believes the eMDR data system and instructions support use of the Voluntary Malfunction Summary Reporting Program for such products. Accordingly, we are including device-led combination products in the Voluntary Malfunction Summary Reporting Program. However, combination product applicants for drug and biologic-led combination products with a device constituent part must submit malfunction reports under a different system. Under § 4.104(b), malfunction reports must be submitted in accordance with 21 CFR 314.80(g) or 600.80(h) for these combination products. Additional considerations, including the issues raised in comments as discussed above, need to be addressed before drug and biologic-led combination products could be included in the Voluntary Malfunction Summary Reporting Program. As noted above, the Agency intends to delay enforcement of the malfunction reporting requirements for drug and biologic-led combination products under the PMSR final rule. FDA will consider all relevant comments submitted on the 2017 Proposal as well as those submitted on the PMSR draft guidance in developing an approach for voluntary malfunction summary reporting for such combination products.

F. Submission Schedule and Logistics

(Comment 18) One comment recommended that FDA permit manufacturers to submit individual reports for each adverse event within 90 calendar days from the date they become aware of the reportable event, while using the summary format. The comment also suggested that FDA provide an additional 30 days for the submission of summary reports because the manufacturer may need more than a month between the end of the reporting period and the due date to aggregate reports.

(Response 18) FDA disagrees with this comment. Permitting manufacturers to submit individual reports using the summary format within 90 calendar days would delay the submission of malfunction information to FDA without providing the anticipated benefits of summary reporting that FDA identified in the 2017 Proposal, such as increased efficiency in processing malfunction reports and more readily apparent malfunction trends. While we recognize that a manufacturer may become aware of some reportable malfunction events toward the end of a quarter, manufacturers will have at least 30 days from that time to prepare and submit summary malfunction reports. FDA does not believe that manufacturers will need an additional 30 days beyond the reporting schedule outlined in the 2017 Proposal to aggregate malfunction reports into a summary report. Therefore, we have retained the Summary Malfunction Reporting Schedule that was included in the 2017 Proposal (see table 1).

(Comment 19) One comment suggested that FDA use a more generic reporting number format or a completely different reporting number format.

(Response 19) FDA disagrees with this comment. The required reporting number format for this program uses the existing common format that manufacturers must use to submit individual reports through their electronic reporting systems under part 803. Therefore, we believe there is no need for a separate MDR reporting number format to identify summary reports.

(Comment 20) One comment suggested that FDA clarify what the manufacturer should do if an investigation is not completed within the reported timeframe.

(Response 20) As discussed in response to Comment 15, FDA has revised the alternative to include instructions regarding supplemental reporting for summary reports submitted under this voluntary program. In situations where a manufacturer is not able to complete its

investigation regarding a reportable malfunction by the deadline for submitting a summary report, the manufacturer is still required to report the event within the timeframes specified in the Summary Malfunction Reporting Schedule (see table 1). If additional information becomes known or available to the manufacturer after submission of a summary report, including additional information that becomes known through an investigation, the manufacturer is required to submit supplemental reports amending its initial submission as needed.

G. Addition of Product Codes to the Program

(Comment 21) Some comments suggested that FDA should explain more clearly how industry would make a request under § 803.19(b) and provide a mechanism for industry to request an exemption, when appropriate, for product codes that may be newly assigned within the first 2 years.

(Response 21) FDA is not making any changes to the alternative in response to this comment. As discussed in section VI, FDA intends to periodically assess the eligibility of product codes after they have been in existence for 2 years and will update the FDA's Product Classification database accordingly. Manufacturers can also send a request for a product code to be added to the list of eligible product codes and for manufacturers of devices within that product code to be granted the same alternative for malfunction events associated with those devices. Information about where to send such requests is provided in section VI.

H. Other Comments

(Comment 22) One comment stated that the average Paperwork Reduction Act (PRA) burden on manufacturers of 6 minutes per response appears to be a very low estimate.

(Response 22) FDA disagrees with this comment. The estimation of time is the amount of time needed to submit a summary malfunction report. It is essentially the same amount of

time needed to submit an individual report because the event narrative should be similar, with the exception of one additional line that is entered that indicates the number of adverse events represented by the report. It does not include the time needed to evaluate and investigate complaints that may represent reportable malfunction events.

(Comment 23) Two comments suggested that FDA should provide clarity on how the program will apply with national competent authorities via the National Competent Authority Report (NCAR) exchange program.

(Response 23) FDA disagrees with this comment. The NCAR exchange program is separate from FDA's MDR reporting requirements. Malfunction summary reporting under this program does not change the information shared through the NCAR exchange program, and the NCAR program is currently outside the scope of the Voluntary Malfunction Summary Reporting Program.

(Comment 24) One comment suggests that FDA should use IBM's Watson Platform for Health GxP (Watson) to conduct an analysis to identify the product codes that represent the largest opportunity described in the business case for patients, industry, and FDA instead of other database systems.

(Response 24) FDA disagrees with this comment. Among other reasons, the IBM Watson Platform is not an FDA-owned resource; therefore, it is not logistically feasible for FDA to use this platform to identify product codes eligible for the Voluntary Malfunction Summary Reporting Program at this time.

III. Principles for Malfunction Summary Reporting

Informed by the findings from the Pilot Program for Medical Device Reporting on Malfunctions, FDA identified the following overarching principles for summary reporting of malfunctions:

- The collection of information in summary format should allow FDA to collect sufficient detail to understand reportable malfunction events.
- To increase efficiency, summary malfunction reporting should occur in a common format for the electronic reporting system used.
- 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. Information contained in a summary malfunction report that is protected from public disclosure under applicable disclosure laws would be redacted prior to release of the report.
- Manufacturers should communicate information regarding an imminent hazard at the earliest time possible.
- 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 Voluntary Malfunction Summary Reporting Program remain subject to requirements for establishing and maintaining MDR event files under § 803.18. In addition, under the QS regulation, manufacturers must evaluate, review, and investigate any complaint that represents an MDR reportable event (see § 820.198).

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

IV. Voluntary Malfunction Summary Reporting Program

For the reasons discussed in the 2017 Proposal and in section II, the Agency has determined that, at this time, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act, all devices should remain subject to the reporting requirements of part 803, to protect the public health. However, based on the findings from the 2015 Pilot Program, the Agency's experience with summary reporting programs, its experience with MDR reporting generally, and the comments received on 2017 Proposal, 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, instead of individual, 30-day malfunction reports.

Therefore, under § 803.19, FDA is granting the manufacturers of devices within eligible product codes, as identified in FDA's Product Classification Database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>) on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], an alternative to the reporting requirements at §§ 803.10(c)(1), 803.20(b)(3)(ii), 803.50(a)(2), 803.52, and 803.56 with respect to reportable malfunction events associated with those devices. The list reflects FDA's consideration of a list proposed by industry representatives, consistent with the MDUFA IV Commitment Letter, as well as the comments received on the 2017 Proposal regarding eligible product codes. To assist manufacturers and the public in identifying which product codes are eligible for participation in this voluntary program, FDA's searchable Product Classification Database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>) has been updated to reflect such eligibility. As discussed in section II, FDA is also making some

changes to the conditions of the alternative after considering the comments received on the 2017 Proposal.

The alternative permits manufacturers of devices within eligible product codes to submit malfunction reports in summary format on a quarterly basis for those devices, subject to the conditions of the alternative described in the remainder of this section. Such manufacturers “self-elect” to participate by submitting summary malfunction reports in accordance with the conditions of the alternative. They do not need to submit a separate application to FDA to participate.¹

The remainder of this section describes the following conditions that manufacturers must follow if they choose to submit summary malfunction reports for devices within eligible product codes under the alternative: (1) the conditions under which individual malfunction reports are required; (2) submission of supplemental reports; (3) the format for summary malfunction reports; (4) considerations for combination products; and (5) the schedule and other logistics for submission of summary reports. Because this is an alternative, if a manufacturer does not submit summary reports for reportable malfunction events in accordance with the conditions described in this section, including the reporting schedule and format, then the manufacturer must submit individual malfunction reports in compliance with all requirements under part 803 (unless the manufacturer has been granted a different exemption, variance, or alternative that applies).

A. Events Outside the Scope of this Alternative

The Voluntary Malfunction Summary Reporting Program does not apply to reportable death or serious injury events, which are still required to be reported to FDA within the

¹ We note that the Voluntary Malfunction Summary Reporting Program does not apply to importers or device user facilities. Therefore, requirements under part 803 for importers and device user facilities are unaffected by this alternative. For example, importers will continue to submit individual MDRs to the manufacturer under § 803.40.

mandatory 30-calendar-day timeframe, under §§ 803.50 and 803.52, or within the 5-work day timeframe under § 803.53. Thus, if a manufacturer participating in the 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.

The reporting requirements at § 803.53 also continue to apply to manufacturers participating in the program. Under § 803.53(a), a 5-day report must be filed if a manufacturer becomes aware of an MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Further, under § 803.53(b), if FDA has made a written request for the submission of a 5-day report, the manufacturer must submit, without further requests, a 5-day report for all subsequent reportable malfunctions of the same nature that involve substantially similar devices for the time period specified in the written request. FDA may extend the time period stated in the original written request if the Agency determines it is in the interest of the public health (see § 803.53(b)).

B. Individual Reporting Conditions

Manufacturers of devices in eligible product codes may continue submitting individual, 30-day malfunction reports in compliance with §§ 803.50 and 803.52 if they choose to do so. However, those manufacturers may submit all reportable malfunction events for devices in eligible product codes in the summary format and according to the schedule described below in section IV.D and F, unless one of the following individual reporting conditions applies:

1. A Reportable Malfunction Is Associated With a 5-Day Report

After submitting a 5-day report required under § 803.53(a), all subsequent reportable malfunctions of the same nature that involve substantially similar devices must be submitted as

individual MDRs in compliance with §§ 803.50 and 803.52 until the date that the remedial action has been terminated to FDA's satisfaction. Summary reporting of malfunctions may then resume on the regularly scheduled summary reporting cycle. 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

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 part 806,² all reportable malfunction events of the same nature that involve the same device or a similar device marketed by the manufacturer must be submitted as individual MDRs in accordance with §§ 803.50 and 803.52 until the date that the recall is terminated. After the recall is terminated, summary reporting may resume on the regularly scheduled summary reporting cycle. 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 part 806 (or the date that the manufacturer submits a report of the correction or removal under part 803 or part 1004 instead, as permitted under § 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

² FDA regulations provide that “[e]ach device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) to reduce a risk to health posed by the device or (2) to remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).” We note that under part 806, manufacturers and importers are not required to report a correction or removal that meets the definition of a class III recall under 21 CFR part 7. (See 21 CFR 7.3(g) and (m), 806.2(d) and (j) through (k), and 806.10; see also 62 FR 27183 at 27184.)

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 must include a check box of recall in section H.7 of the electronic Form FDA 3500A.

3. FDA Has Determined That Individual MDR Reporting Is Necessary To Address a Public Health Issue

If FDA has determined 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 in compliance with §§ 803.50 and 803.52. Under these circumstances, FDA will provide written notification to manufacturers of relevant devices that individual MDR submissions are necessary. FDA will provide further written notice when manufacturers of those devices may resume participation in summary malfunction reporting.

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 and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit any of those malfunction events for the identified devices to FDA within 30 calendar days of receiving notification from FDA.

4. FDA Has Determined That a Device Manufacturer May Not Report in Summary Reporting Format

FDA may determine that a specific manufacturer is no longer allowed to participate in the Voluntary Malfunction Summary Reporting Program for reasons including, but not limited to,

failure to comply with applicable MDR requirements under part 803, failure to follow the conditions of the program, or the need to monitor a public health issue. In that case, FDA will provide written notification to the device manufacturer to submit individual malfunction reports in compliance with §§ 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.

5. A New Type of Reportable Malfunction Occurs for a Device

If a manufacturer becomes aware of information reasonably suggesting 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 §§ 803.50 and 803.52. After the manufacturer submits this initial individual report, subsequent malfunctions of this type may be submitted in summary form according to the reporting schedule in table 1, unless another individual reporting condition applies.

C. Supplemental Reports

In general, if a manufacturer obtains information required in a malfunction summary report (see section IV.D. describing the required content of a summary report), that the manufacturer did not provide because it was not known or was not available when the manufacturer submitted the initial summary malfunction report, the manufacturer must submit

the supplemental information to FDA in an electronic format in accordance with § 803.12(a). The supplemental information must be submitted to FDA by the submission deadline described in the Summary Malfunction Reporting Schedule (table 1), according to the date on which the manufacturer becomes aware of the supplemental information. Manufacturers must continue to follow the requirements for the content of supplemental reports set forth at § 803.56(a) through (c), meaning that on 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 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.

However, if a manufacturer submits a summary malfunction report and subsequently becomes aware of information reasonably suggesting that an event (or events) summarized therein represents a reportable serious injury or death event, or a new type of reportable malfunction, then the manufacturer must submit reports as follows: 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 simultaneously submit a supplement to the initial malfunction summary report reducing the number of events summarized accordingly, so that the total number of events remains the same.

D. Malfunction Reporting Summary Format

Manufacturers of devices in eligible product codes who elect to participate in the Voluntary Malfunction Summary Reporting Program must submit summary malfunction reports

in the format described below. As detailed in the 2017 Proposal and Appendix, the format largely adopts the format that was tested in FDA's Pilot Program for Medical Device Reporting on Malfunctions and is compatible with the Form FDA 3500A (Ref. 9), which allows manufacturers to submit MDRs using the same electronic submission form that they use to submit individual MDRs, in accordance with the eMDR Final Rule (79 FR 8832, February 14, 2014). Because summary malfunction reports represent a grouping of malfunction events for a specific model of a device, the summary reporting format would require an additional element in the summary text narrative to identify the number of reportable malfunctions that each report represents. As described below, the XML tags "<NOE>" and "<NOE/>" are placed on both sides of the number of events (NOE) to make the number extractable from the report. FDA believes that submission of summary reports in the format described below will provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively.

Format Instructions: Separate summary malfunction reports must be submitted for each unique combination of brand name, device model, and problem code(s). (See Appendix A for case examples of how to report (Ref. 6).) Each summary malfunction report must include at least the following information collected on Form FDA 3500A and must be submitted in an electronic format:

- SECTION B.5: Describe Event or Problem--To distinguish this report as a summary malfunction report, the first sentence of the device event narrative must read: "This report summarizes <NOE> XXX </NOE> malfunction events," where XXX is replaced by the number of malfunction events being summarized.

The device event narrative must then 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.

- SECTION D.1: Brand Name.
- SECTION D.2 and D.2.b: Common Device Name and Product Code. Include the common name of the device and Product Classification Code (Procode).
- SECTION D.3: Manufacturer Name, City, and State.
- SECTION D.4: Device Identification--Enter the 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 device identifier (DI) portion of the unique device identifier (UDI) for the device version or model that is the subject of the MDR.
- SECTION G.1: Contact Office (and Manufacturing Site(s) for Devices)--Enter the name, address, and email of the manufacturer reporting site (contact office), including the contact 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.
- SECTION G.2: Phone Number of Contact Office.
- SECTION G.5: Combination Products--If applicable, indicate that the report involves a combination product (see section IV.E.).
- 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). (See Appendix A for case examples of how to report (Ref. 6).)

- Enter the evaluation code(s) for the following categories: Method, Results, Conclusion.
- Enter a Conclusion Code, even if the device was not evaluated.
- SECTION H.10: 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, including 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).

E. Combination Product Considerations

As noted in the response to comment 17 above, device-led combination products are included in this alternative that we are granting under § 803.19 to permit voluntary malfunction summary reporting. The eMDR data system and instructions support use of the Voluntary Malfunction Summary Reporting Program for device-led combination products. However, as discussed in response to comment 17 above, additional considerations need to be addressed before drug and biologic-led combination products could be included in the Voluntary Malfunction Summary Reporting Program. As noted in Response 17, the Agency intends to delay enforcement of the malfunction reporting requirements for drug and biologic-led combination products under the PMSR final rule. FDA will consider the relevant comments received on the 2017 Proposal, as well as any additional, relevant comments relating to malfunction reporting for drug and biologic-led combination products submitted in relation to the

PMSR draft guidance in developing an approach for voluntary malfunction summary reporting for such combination products.

F. Submission Schedule and Logistics

Manufacturers submitting malfunction summary reports or supplemental reports to a malfunction summary report must use electronic reporting (Ref. 10) to submit those reports 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 the first column of table 1.

Table 1.--Summary Malfunction Reporting Schedule

Reportable malfunctions or supplemental information that you become aware of during these timeframes:	Must be submitted to 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

The Voluntary Malfunction Summary Reporting Program applies only to reportable malfunction events that manufacturers become aware of on or after [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The deadline for FDA accepting the first round of quarterly reports for this program is October 31, 2018.

Under §§ 803.17 and 803.18, manufacturers are required to develop, maintain, and implement written MDR procedures and establish and maintain MDR event files, and those requirements remain applicable for manufacturers that elect to participate in this program. Among other things, a manufacturer must develop, maintain, and implement MDR procedures that provide for timely transmission of complete MDRs to FDA. (See § 803.17(a)(3)).

Manufacturers participating in the Voluntary Malfunction Summary Reporting Program will need to update their internal MDR processes and procedures to provide for submitting summary malfunction reports within the Summary Malfunction Reporting Schedule.

V. Implementation Strategy

The goal of the Voluntary Malfunction Summary Reporting Program is to permit manufacturers of devices under certain product codes to report malfunctions on a quarterly basis and in a summary format, as outlined in the MDUFA IV Commitment Letter (Ref. 1), in a manner that provides for effective monitoring of devices and is beneficial for FDA, industry, and the public. An important part of this voluntary program is providing clarification to manufacturers regarding the product codes eligible for the program.

Consistent with the MDUFA IV Commitment Letter (Ref. 1), FDA has identified eligible product codes for the Voluntary Malfunction Summary Reporting Program in FDA's Product Classification Database, available on FDA's website, as part of granting the alternative (see <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>). Manufacturers that choose to participate in quarterly, summary reporting through this program will remain responsible for complying with applicable MDR requirements under part 803 (e.g., requirements to establish and maintain MDR event files under § 803.18) and QS requirements under part 820 (21 CFR part 820) (e.g., the requirement to evaluate, review, and investigate any complaint that represents an MDR reportable event under § 820.198).

If FDA determines that individual malfunction reports are necessary from a specific manufacturer or for specific devices, FDA will notify relevant manufacturers that they must submit individual reports and provide an explanation for that decision and, as appropriate, the steps necessary to return to summary, quarterly reporting. The Agency also notes that, under

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

VI. Updating Product Codes for Inclusion Into the Program

FDA recognizes that new product codes will be created after the date of granting the Voluntary Malfunction Summary Reporting Program alternative under § 803.19. In general, FDA does not intend to consider devices under product codes in existence for less than 2 years to be eligible for the program, unless the new product code was issued solely for administrative reasons. Any product code in existence after the publication date will be initially ineligible to participate in the program. However, FDA will periodically evaluate new product codes after they have been in existence for 2 years to determine whether they should be added to the list of product codes eligible for the Voluntary Malfunction Summary Reporting Program. If FDA determines that a new product code should be added, then it will grant manufacturers of devices within that product code the same alternative under § 803.19 for malfunction events associated with those devices and update FDA's Product Classification database accordingly to reflect the changes.

Manufacturers can send a request for a product code to be added to the list of eligible product codes and for manufacturers of devices within that product code to be granted the same alternative for malfunction events associated with those devices to the MDRPolicy@fda.hhs.gov mailbox. You may also mail your written request to MDR Policy Branch, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3217, Silver Spring, MD 20993-0002.

VII. Conclusion

In accordance with section 519(a)(1)(B)(i) of the FD&C Act and § 803.19, FDA is granting the alternative described in section IV to manufacturers of devices in eligible product codes, as identified in the FDA Product Classification Database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>) on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. FDA believes that for the devices in eligible product codes, quarterly, summary reporting in accordance with the conditions of the alternative will be as effective as the current MDR regulatory requirements for purposes of identifying and monitoring potential device safety concerns and device malfunctions. The Voluntary Malfunction Summary Reporting Program will allow manufacturers to submit summary reports with event narratives that will help FDA more efficiently process malfunction reports and identify malfunction trends. In addition, FDA's determination of product code eligibility and the conditions of participation in the program will require submission of individual 30-day or 5-day malfunction reports in circumstances where such reports are necessary to protect public health.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

The Voluntary Malfunction Summary Reporting Program described in this Notice contains information collection provisions 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). These provisions have been approved under OMB control number 0910-0437.

This document also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA (44 U.S.C. 3501-3520). The collections of information in part 4, subpart B, regarding postmarketing safety reporting for combination products have been approved under OMB control number 0910-0834; the collections of information in part 803, regarding medical device reporting, have been approved under OMB control number 0910-0437; the collections of information in 806, regarding corrections and removals, have been approved under OMB control number 0910-0359; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 810, regarding medical device recall authority, have been approved under OMB control number 0910-0432; the collections of information in part 820, regarding quality system regulations, have been approved under OMB control number 0910-0073; the collections of information in 21 CFR parts 1002 through 1050, regarding radiological health, have been approved under OMB control number 0910-0025; the collections of information regarding the MedWatch: The Food and Drug Administration Medical Products Reporting Program have been approved under OMB control number 0910-0291; and the collections of information regarding the Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)) have been approved under OMB control number 0910-0471.

X. References

The following references are on display in the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Medical Device User Fee Agreement IV Commitment Letter, available at <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf>.

2. Food and Drug Administration, "Medical Device Reporting--Alternative Summary Reporting (ASR) Program; Guidance for Industry," (October 19, 2000); available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072102.pdf>.

3. Food and Drug Administration, "Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff," (November 8, 2016); available at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf>.

4. Food and Drug Administration, "Center for Devices and Radiological Health Appeals Processes; Guidance for Industry and Food and Drug Administration Staff," (May 17, 2013); available at

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf>.

5. Food and Drug Administration, “International Medical Device Regulators Forum,” available at

<https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm>.

6. Appendix A, “Case Examples of Summary Malfunction Reporting,” available in Docket No. FDA-2017-N-6730.

7. Food and Drug Administration, “Postmarketing Safety Reporting for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff,” (March 2018); available at

<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM601454.pdf>.

8. Food and Drug Administration, “Compliance Policy for Combination Product Postmarketing Safety Reporting, Immediately in Effect Guidance for Industry and Food and Drug Administration Staff,” available at

<https://www.fda.gov/RegulatoryInformation/Guidances/ucm601456.htm>.

9. Food and Drug Administration, Form FDA 3500A, available at <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm048334.pdf>
f. 5.

10. Electronic Medical Device Reporting (eMDR) (manufacturers may obtain information on how to prepare and submit reports in an electronic format that FDA can

process, review, and archive), available at:

<https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm>.

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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