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February 6, 2023

Via Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. FDA-2022-D-2873*, Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff*

To Whom It May Concern,

On behalf of the Medical Device Manufacturers Association (MDMA), below please find comments on the Draft Guidance for Industry and Food and Drug Administration (FDA) Staff, *Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers*.

MDMA is a national trade association that provides educational and advocacy assistance to hundreds of innovative companies in the field of medical technology. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering breakthrough therapies to treat chronic diseases and life-threatening conditions while lowering the cost of care. MDMA's mission is to ensure that patients have timely access to the latest advancements of safe and effective medical technologies that improve health outcomes.

We appreciate the opportunity to submit these comments, and we look forward to ongoing collaboration with FDA to address this important topic.

MDMA supports the goals of the VMSR program and believes that the draft guidance is suitable in principle, but that FDA should further streamline the process to enhance participation in the program. We have several recommendations that we hope will further improve upon the draft guidance.

- First, the draft guidance provides only minimal information regarding the requirements for submitting reports using Form FDA 3500A. MDMA recommends that FDA publish additional guidance outlining these essential requirements to provide notice to stakeholders as to how to participate in the VSMR program and to facilitate consistent application of the essential requirements of the summary reports from reporters to FDA. MDMA further encourages FDA to work with major Complaint Handling Software companies to facilitate the development of information technology (IT) solutions capable of supporting VMSR.

- Second, the draft guidance states that malfunction summary reports must be submitted for each unique combination of device brand name, device model, and medical device problem code. MDMA suggests it would be more efficient to allow reports to be sent for each unique device brand name or model only and not to require separate submissions for each unique combination of brand name, model, and product problem experienced. Under this approach, manufacturers would still provide all of the problem codes reported for that device or model and ensure that the required details regarding device performance are submitted. However, this approach would be more streamlined and reduced the burden on both FDA and manufacturers. The approach proposed in the draft guidance would instead require industry submission and FDA review of multiple summary reports for a specific device based on individual problems and unique combinations of those same problems. Similarly, FDA could establish a new medical device report (MDR) form allowing for multiple brand names, devices, models, and problem codes to be included in one document where all the necessary data could be attached in an excel file with standardized columns. A new MDR data entry form designed specifically for summary reports would assist in providing improved functionality and usability of summary reporting as well as subsequent data analytics.

- Third, the draft guidance states that if a manufacturer becomes aware of information that reasonably suggests an event in a previously-submitted malfunction summary report represents a reportable serious injury or death, the manufacturer is required to simultaneously submit both an individual MDR within 30 calendar days for the identified serious injury or death and a supplemental summary report to update the initial malfunction summary report. We recommend that when an event has previously been submitted in a malfunction summary report then requires an individual MDR, the 30 calendar day timeframe should apply to the MDR but manufacturers should not be required to submit the malfunction summary report simultaneously. Rather, we believe manufacturers should be allowed to supplement the malfunction summary report consistent with the existing Summary Malfunction Reporting Schedule. This approach would reduce burdens on manufacturers while ensuring that the Agency promptly receives notice of these events, as FDA would nonetheless be notified of the event within 30 calendar days through the individual report. Permitting manufacturers to submit supplements on the quarterly schedule would allow manufacturers to report supplementary information consistent with their current obligations and avoid the need for manufacturers to update event numbers outside of the established cadence for such reporting.

We appreciate the opportunity to comment on this draft guidance. If we can provide any additional information, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahey
President & CEO
Medical Device Manufacturers Association

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February 7, 2023

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: ***Docket No. FDA-2022-D-2873; Draft Guidance for Industry and FDA Staff on Voluntary Malfunction Summary Reporting Program for Manufacturers***

Dear Sir or Madam:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment in response to the Food and Drug Administration (FDA) "Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers" (hereinafter "VMSR Guidance" or "draft guidance"). AdvaMed represents manufacturers of medical devices and diagnostic products that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers.

AdvaMed appreciates FDA (or "Agency") efforts in establishment of a summary reporting program for device malfunctions. This program is intended to meet the goals outlined in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter to establish criteria to streamline medical device reporting (MDR) requirements for "most, if not all" device procodes as well as statutory directive for summary quarterly reporting under section 227 of the Food and Drug Administration Amendments Act of 2007.

We support the aims of the program to benefit FDA, the public, and manufacturers through helping FDA to process the information it receives more efficiently to facilitate understanding of potential malfunction issues, increasing transparency to the public, and helping reduce the burden on manufacturers. Further, we appreciate the development of guidance to better understand and use the VMSR Program. While we note the expanded scope of product codes (or procodes) since inception of the program, eligibility and related restrictions of the VMSR Program can be a limiting factor for manufacturers' participation and thus impact some efficiencies that might be gained from the program.

As part of FDA efforts to further explain the conditions of the VMSR Program, we believe a useful and reasonable step would be to publish a clear list of inclusion/exclusion criteria based on all relevant code types to add clarity in eligibility considerations. This would help provide direction beyond types of excluded events (e.g., "infection") and clearly delineate what is included or eligibility based on the same procode, problem code, and cause code. We note company participants have already invested or will be investing significant IT infrastructure and system design to accommodate the VMSR Program and thus clear and consistent eligibility criteria will encourage understanding and increased utility of the program.

While eligible procodes can be found in the Product Classification Database, it would also be helpful in furtherance of FDA efforts to help manufacturers better understand and use the program to provide a list of codes eligible for VMSR reporting directly on the FDA website. This eligible code list could be updated as needed and serve as a ready complement to the guidance.

We also note the integration of capabilities, such as the option to use Excel spreadsheets for summary reporting, would increase efficiencies and allow for a single report than separate reports for each grouping. This would also allow end users to efficiently review and analyze the data. We believe these recommendations are consistent with the goals of the VMSR Program and could be integrated or cross-referenced in the guidance.

Further specific comments can be found in the attached table. They are intended to assist industry and FDA to further understand and utilize the VMSR Program.

AdvaMed greatly appreciates the opportunity to provide comment. We believe that our comments will aid clarity and meaningful implementation of the guidance. Please do not hesitate to contact me at 202-434-7267 or kcalleja@advamed.org if you have any questions.

Sincerely,

Khatereh Calleja

Khatereh Calleja
Vice President
Technology and Regulatory Affairs

ADVAMED SPECIFIC COMMENTS

on Draft Guidance for Industry and FDA Staff—
Voluntary Malfunction Summary Reporting Program (VMSR)
for Manufacturers

Edit No.	Line No.	Comment/Change	Rationale
1.	146-148	Clarify the case when a manufacturer may choose to no longer participate ("opt out") in the VMSR Program. Specifically, is any notification required to FDA?	Factors involving systems, staffing, or product reporting levels may cause a manufacturer to reconsider participation. It is clear in the guidance that no application is needed for participation, but it is not evident what is expected when a company may no longer choose to participate.
2.	176-177	Further define "periodically." Is this weekly, quarterly, annually?	This could help manufacturers anticipate when a change to eligibility may occur and avoid sudden/unanticipated change in reporting method.
3.	342	Clarify what is meant by "[w]here root causes of malfunction events are not well understood." Does this mean where the FDA determines a root cause is not well understood and notifies the manufacturer that individual MDRs are needed for the issue, or where the manufacturer has not determined clear root causes for the malfunction event?	Clarification is needed. If specific to the second case (where the manufacturer has not determined clear root causes for the malfunction event), this could result in manufacturer reporting individually due to root cause not being known within 30 days.
4.	355-358	Clarify the format in which these malfunction events should be submitted within 30 calendar days (i.e., as individual reports or as a summary report).	Specificity would be helpful here.
5.	408-409	Clarify the unique combination applies to only the Medical Device Problem Code. While the codes covered under 446-452 (Adverse Event Problem) would be included in the summary	This is consistent with the Final VMSR Notice, which states "each unique combination of… problem code(s)." This implies that the unique combination applies to only the Medical Device Problem Code (e.g., all leaks for a specific device model

Edit No.	Line No.	Comment/Change	Rationale
		report, "unique combination of… MDR adverse event code(s)" would not mean each unique combination of adverse event codes (Medical Device Problem, Type of Investigation, Investigation Findings, and Investigation Conclusions codes).	could be included in one summary report, regardless of the investigation codes associated with the leak).