■ i. Removing ''$78'' and adding ''$80'' in its place; and
■ ii. Removing ''$39'' and adding ''$40'' in its place.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2024–19431 Filed 8–28–24; 8:45 am]

BILLING CODE 6750–01–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 for Manufacturers

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification; order granting modification to alternative.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing a minor, technical modification to 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.''

DATES: This modification applies to voluntary summary reports for reportable malfunction events that manufacturers become aware of on or after August 29, 2024.

FOR FURTHER INFORMATION CONTACT: Michelle Rios, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1116, Silver Spring, MD 20993–0002, 301–796–6107; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Every year, FDA receives over two million 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 most 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, that 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.''

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 accordance with section 519(a)(1)(B)(i) of the FD&C Act and § 803.19, FDA granted 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 August 17, 2018, an alternative that permits submission of malfunction summary reports on a quarterly basis for certain device malfunctions. The Agency published a document of the alternative in the **Federal Register** (83 FR 40973, August 17, 2018). Consistent with that document, FDA subsequently determined that additional product codes are eligible for the Voluntary Malfunction Summary Reporting Program (the program) and granted the same alternative to manufacturers of devices in those product codes.

FDA believes that for the devices in eligible product codes, quarterly, summary reporting in accordance with the conditions of the alternative is as effective as the current MDR regulatory requirements for purposes of identifying and monitoring potential device safety concerns and device malfunctions. The program allows manufacturers to submit summary reports with event narratives that 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 serve to require submission of individual 30-day or 5-day malfunction reports in circumstances where such reports are necessary to protect public health.

II. Modification to Malfunction Summary Reporting Format for the Voluntary Malfunction Summary Reporting Program

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

To meet the conditions of the Voluntary Malfunction Summary Reporting Program (VMSR), manufacturers of devices in eligible product codes who elect to participate in the program must submit summary malfunction reports electronically using Form FDA 3500A (Ref. 1) pursuant to the malfunction reporting summary format described in the document published in 2018 (83 FR 40973, August 17, 2018). However, since the program began in 2018, FDA has revised Form FDA 3500A. For example, FDA has added a ''check box'' and field in which the manufacturer may specifically indicate that a report is a ''summary report'' and enter the number of events being summarized. Additionally, FDA has added a field that facilitates clearer identification of a report as a VMSR summary reports. Use of these features of the revised Form 3500A allows FDA to more efficiently identify VMSR summary reports and the number of events summarized, enabling more effective review of these reports. Certain fields in the Form FDA 3500A have also changed so that they no longer align exactly with the instructions describing the required malfunction reporting summary format for the program. In addition, FDA's MDR references for adverse event codes have been updated.

Revising the required format for summary malfunction reports submitted under the VMSR Program to align with the most current Form FDA 3500A and adverse event codes will avoid confusion and help ensure the accuracy and consistency of information in summary malfunction reports. Consistent, accurate summary reports are necessary to ensure that both FDA

and the public are able to find information about device malfunctions and identify malfunction trends more readily. Therefore, we have determined that modifying the malfunction reporting summary format under § 803.19(d) to align with the revised Form FDA 3500A and updated references for MDR adverse event codes is necessary to protect the public health. Specifically, we are making the following changes:

- Use of dedicated fields to identify the report as a VMSR summary malfunction report. Instead of using XML tags ''<NOE> XXX <NOE>'' in the ''Describe Event or Problem'' section of Form FDA 3500A, manufacturers must use the following fields:
  - In the ''Exemption/Variance Number'' field, include the term ''VMSR.''
  - In the ''Type of Reportable Event'' section of the Form FDA 3500A, check the ''Summary Report'' box and identify the number of events in the ''Number of Events Summarized'' field.
- Update the adverse events code references, from Method, Results and Conclusions to ''Type of Investigation'', ''Investigation Findings'', and ''Investigation Conclusions''.
- Remove references to the specific number identifiers for the Form FDA 3500A sections from the description of the malfunction summary reporting format and individual reporting conditions (as applicable) to remove inconsistency with the current version of the Form FDA 3500A. The sections are instead identified only by description name.

III. Voluntary Malfunction Summary Reporting Program

FDA is republishing the conditions that manufacturers must follow if they choose to participate in the Voluntary Malfunction Summary Reporting Program with the changes described in section II of this document incorporated, along with a few editorial changes for clarity. Under § 803.19, FDA has granted 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*), 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 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 revised 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 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 III.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 (21 CFR part 806), 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. As stated in 21 CFR 806.10(a), FDA regulations require

[1] We note that the Voluntary Malfunction Summary Reporting Program does not apply to importers or device user facilities. Therefore, requirements under 21 CFR 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.

that manufacturers submit a written report to FDA of any correction or removal of a device by the manufacturer if it was initiated to reduce a risk to health posed by the device; or 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 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 part 7 (21 CFR part 7). (See §§ 7.3(g) and (m), 806.2(d) and (j) through (k), and 806.10(a); see also 62 FR 27183 at 27184.) 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 21 CFR 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 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 indicate the check box of recall in the ''Remedial Action Initiated, Check Type'' in 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 notification 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 to FDA 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 III.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

As discussed in section II, we are revising the malfunction summary reporting format to reflect updates to the

Form FDA 3500A (Ref. 1) and to FDA's references to MDR adverse event codes. While some aspects of the format in which manufacturers must submit their summary reports will change, the information required to be submitted by participating manufacturers will not.

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. 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.

Separate summary malfunction reports must be submitted for each unique combination of brand name, device model, and MDR adverse event device problem code(s).

Each summary malfunction report must include at least the following information collected on Form FDA 3500A and must be submitted in an electronic format:

- Exemption/Variance Number—Type in ''VMSR''.
- Describe Event or Problem—The device event narrative must include a detailed description of the nature of the events and, if relevant and available, we recommend including a range of patient age and weight and a breakdown of patient gender, race, and ethnicity. Inclusion of patient age, weight, gender, race, and ethnicity is not a required entry for the form; however, FDA recommends including these descriptors in a text narrative if the information is available and if a malfunction is more likely to affect a specific group of patients.
- Brand Name—Include the device brand name.
- Common Device Name and Product Code—Include the common name of the device and its product code.
- Manufacturer Name, City, and State—Add the manufacturer's name and identify its location.
- Model Number and other device identifying information—Enter the device model and/or catalog number and lot number(s) and/or serial number(s) for the devices that are the subject of the MDR. Include any device identifier (DI) portion of the unique device identifier for the device version or model that is the subject of the MDR.
- 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.
- Phone Number of Contact Office—Include a phone number for the contact office.
- Combination Products (if applicable)—Check if the report involves a combination product.
- Type of Reportable Event—Check ''Malfunction.'' Manufacturers must check the ''Summary Report'' box and identify the number of events being summarized.
- Adverse Event Problem—Enter the corresponding codes, including as many codes as necessary to describe the event problem and evaluation for the reportable malfunction events that are being summarized:
  - ''Medical Device Problem Code''
  - ''Type of Investigation''
  - ''Investigation Findings''
  - ''Investigation Conclusions,'' even if the device was not evaluated.
- Additional Manufacturer Narrative—Provide a summary of the results of the investigation for the reported malfunctions, including any follow up actions taken, and any additional information that would be helpful in understanding how the manufacturer addressed the malfunction events summarized in the report. Enter a breakdown of the malfunction events summarized in the report: the number of devices that were returned, the number of devices that were labeled ''for single use'' (if any), and the number of devices that were reprocessed and reused (if any).

E. Combination Product Considerations

Device-led combination products are included in this alternative. The electronic Medical Device Reporting (eMDR) data system and instructions (Ref. 2) support use of the Voluntary Malfunction Summary Reporting Program for device-led 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. 2) 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.

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 must update their internal MDR processes and procedures to provide for submitting summary malfunction reports within the Summary Malfunction Reporting Schedule.

IV. Program Implementation

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 Medical Device User Fee Agreement (MDUFA) IV Commitment Letter (Ref.

3), 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. 3), FDA has identified eligible product codes for the Voluntary Malfunction Summary Reporting Program in FDA's Product Classification Database, available on FDA's website *https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/voluntary-malfunction-summary-reporting-program.* 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 quality system 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.

V. Updating Product Codes for Inclusion Into the Program

FDA recognizes that new product codes will be created in the future. In general, as explained in the document published in 2018 (83 FR 40973, August 17, 2018), FDA does not intend to consider devices under product codes in existence for fewer than 2 years to be eligible for the program, unless the new product code was issued solely for administrative reasons. 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.

VI. Conclusion

In accordance with section 519(a)(1)(B)(i) of the FD&C Act and § 803.19(d), FDA is modifying the alternative granted to manufacturers of devices in eligible product codes, as identified in the FDA's Product Classification Database, available on FDA's website *https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/voluntary-malfunction-summary-reporting-program,* for the Voluntary Malfunction Summary Reporting Program. Specifically, we are modifying the malfunction summary reporting format to enhance consistency with the revised Form FDA 3500A and to update FDA references to MDR adverse event codes, as well as to make a few editorial changes for additional clarity. This modification will help ensure the accuracy and consistency of summary malfunction reporting information submitted to FDA and thus help protect the public health.

VII. 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.

VIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA. MedWatch Form FDA 3500A. Available at: *https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.*
2. FDA. Electronic Medical Device Reporting (eMDR) website. Available at: *https://www.fda.gov/industry/fda-esubmitter/electronic-medical-device-reporting-emdr.*
3. * FDA. Medical Device User Fee Agreement IV Commitment Letter. Available at: *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*

Dated: August 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19414 Filed 8–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0559]

RIN 1625–AA00

Safety Zone; West Passage Narragansett Bay, Jamestown, RI

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 250-yard radius of the MARMAC 306 cable laying barge, and a J.F. Brennan construction barge #4132. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by cable laying operations being conducted in the vicinity of the West Passage Narragansett Bay, Jamestown, RI, between the Jamestown Verrazzano Bridge and south to Dutch Island. When enforced, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Southeastern New England.

DATES:

Effective date: This temporary interim rule is effective from 12:01 a.m. on September 1, 2024, through 11:59 p.m. on December 31, 2024. The rule will