food that does not include food for cats, dogs, vitamin premixes, or aquaculture.

Interested persons were originally given until October 23, 2017, to comment on the petitioner's environmental assessment. The environmental assessment was not placed on public display until October 13, 2017. On our own initiative, we are reopening the comment period to allow potential respondents to thoroughly evaluate and address pertinent environmental issues.

Dated: December 20, 2017

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27789 Filed 12–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA–2017–N–6730]

Center for Devices and Radiological Health; Medical Devices and Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health and Center for Biologics Evaluation and Research, is announcing a proposed program for manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form—the Voluntary Malfunction Summary Reporting Program. This proposed 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 Act of 2017 (MDUFA IV Commitment Letter). These goals include permitting manufacturers of devices in certain product codes to report malfunctions on a quarterly basis and in a summary format. In addition, this proposed program reflects FDA's findings from a pilot program the Agency conducted to study summary reporting formats for malfunction MDRs.

DATES: Submit either electronic or written comments on this notification by February 26, 2018. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 26, 2018. See section IV of this document, the ''Paperwork Reduction Act of 1995.''

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 26, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 26, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–6730 for ''Voluntary Malfunction Summary Reporting Program for Manufacturers.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.
- *Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isaac Chang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3114, Silver Spring, MD 20993, 301–796–6670, *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 post-market 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.

The regulations contained in part 803 (21 CFR part 803) and issued under section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) set forth medical device reporting requirements. 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 (see §§ 803.10(c)(1) and 803.50(a)(2) (21 CFR 803.10(c)(1) and 803.50(a)(2))). 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. (See § 803.19(c).)

FDA has historically granted exemptions, variances, and/or alternatives under § 803.19 to allow a variety of summary reporting methods for select types of MDRs. For example, in October 2000, FDA issued guidance on the Alternative Summary Reporting (ASR) Program (Ref. 1). Through the ASR program, FDA has granted an exemption from individual reporting requirements of §§ 803.50 and 803.52 to certain manufacturers, allowing them to efficiently submit reportable events in a compact manner. As a condition of exemptions, variances, or alternatives that FDA has granted in the past, device manufacturers were required to submit certain MDR reportable events to FDA in a ''line item'' spreadsheet format consisting mainly of event codes (Ref. 2). Although the summary reports contained this abridged data, as part of the request for an exemption, variance, or alternative, FDA also received a narrative description of the types of events that would be summarized in these reports.

While FDA had sufficient understanding of the summary reports using the ''line item'' spreadsheet format, the Agency noted that the absence of a narrative in summary reports would make it more difficult for the public to interpret the coding in the summary reports and understand the context of the MDR using the publicly accessible MDR database. For example, a report with codes indicating corrosion and electrical issues may be difficult to interpret because this could be interpreted as: (1) Corrosion leading to an electrical issue, (2) an electrical issue leading to corrosion, or (3) an indeterminate relationship between the corrosion and electrical issue. However, with the inclusion of event narratives, this information is more easily understood. As a result, FDA believes it is important to include narratives in summary reporting to facilitate public understanding of the information and promote transparency in the publicly accessible MDR database.

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—with the exception of 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 must 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 in order to protect the public health, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act. Consequently, unless granted an individual exemption, variance, or alternative, manufacturers of those devices have continued to be required to submit individual malfunction reports under part 803, as was required pre-FDAAA.

To facilitate exploration of an appropriate format for collecting malfunction reports in summary form, FDA announced in the **Federal Register** of August 18, 2015 (80 FR 50010), a ''Pilot Program for Medical Device Reporting on Malfunctions.'' In that document, FDA solicited volunteers for participation in the pilot program for the submission of MDRs in summary format on a quarterly basis for malfunctions of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining. The announcement provided a comprehensive description of the pilot, the guiding principles, conditions, and examples of how to fill out the summary reports in different situations. The summary reporting format used in the pilot was an adaptation of the full electronic Form FDA 3500A, which included event and manufacturer narratives (Ref. 3). In the pilot summary reporting format, one line was appended to Section B5 (''event narrative'') that identified the number of events represented by the report. Reports were summarized for each model/catalog number of the device for each device problem type.

The pilot demonstrated several important findings. First, participants were able to reduce the volume of reports by over 87 percent using the pilot format, while preserving the essential information regarding the context around malfunction events. This increased efficiency in reporting and in the Agency review and processing of malfunction reports. The format also allowed for simple, transparent, and cost-effective reporting through existing electronic reporting processes for submission of electronic MDRs (eMDRs)

to FDA, in accordance with the Medical Device Reporting: Electronic Submissions Requirements Final Rule (eMDR Final Rule) published in the **Federal Register** of February 14, 2014 (79 FR 8832). Based upon observations from the pilot experience, this summary format was usable for both large and small firms with varying numbers of marketed devices. Lastly, summary reports collected in this format could be more easily shared publicly, facilitating transparency of malfunction reporting.

Consistent with these findings, FDA believes that bundling ''like events'' together into a single summary report description would have benefits for manufacturers, FDA, and the public. For many manufacturers, this approach would greatly reduce the volume of reports that they would need to submit to FDA. For FDA, information would be received in a streamlined manner that would facilitate more efficient understanding of malfunction issues. For the public, summary reports could make malfunction event trends for a particular device more readily transparent. In the MDUFA IV Commitment Letter (Ref. 4), FDA and industry agreed to certain goals for streamlining malfunction reporting that would help achieve these benefits. These goals include permitting manufacturers of devices in certain product codes to report malfunctions on a quarterly basis and in a summary format. FDA also agreed to publish a list of device product codes for which manufacturers would be eligible to submit malfunction reports on a quarterly basis and in a summary MDR format. As explained in the MDUFA IV Commitment Letter, this list is to include product codes for class II implantable devices and class III devices, as appropriate, and reflect FDA's consideration of a list proposed by industry representatives.

II. Principles for Malfunction Summary Reporting

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

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

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

3. Information about reportable malfunctions should be transparent to FDA and to the public, regardless of whether the information is reported as an individual MDR or a summary report. 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.

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

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

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

III. Proposed Voluntary Malfunction Summary Reporting Program

Based on the findings from the 2015 Pilot Program, the Agency's experience with summary reporting programs, and its experience with MDR reporting generally, FDA has determined it is appropriate to expand the opportunity to participate in summary malfunction reporting, consistent with the principles identified above. The Agency believes that for many types of reportable malfunctions, submission of summary reports on a quarterly basis would allow FDA to collect sufficient detail to monitor devices effectively. Currently, however, there are still situations in which submission of individual malfunction reports on a more prompt 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 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. Thus, the Agency has determined that, at this time, all devices should remain subject to the reporting requirements at part 803, to protect the public health.

To expand the opportunity to participate in summary malfunction reporting, FDA is proposing that under § 803.19, manufacturers of devices within eligible product codes would be granted an alternative to the reporting requirements at §§ 803.10(c)(1), 803.20(b)(3)(ii), 803.50(a)(2), and 803.52 with respect to reportable malfunction events associated with those devices. FDA is also considering how this proposed alternative may apply to combination products, and seeks comment on this issue (see 21 CFR 3.2(e) for definition of combination products and 21 CFR part 4, subpart B, for postmarketing safety reporting requirements for combination products). This proposed alternative would permit manufacturers to submit malfunction reports for devices within eligible product codes in summary format on a quarterly basis, subject to certain conditions. The proposed Voluntary Malfunction Summary Reporting Program would not apply to importers or device user facilities. Therefore, requirements under part 803 for importers and device user facilities would be unaffected. For example, importers will continue to submit individual MDRs to the manufacturer under § 803.40.

The remainder of this section describes the following aspects of the proposed program: (1) The conditions of participation in the program, (2) the format for summary malfunction reports, (3) the schedule and other logistics for submission of summary reports, (4) FDA's proposed implementation strategy for the program, and (5) adding to the list of product codes eligible for the program.

A. Program Conditions

The proposed Voluntary Malfunction Summary Reporting Program would 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 proposed program became aware of information reasonably suggesting that a device that it markets has malfunctioned, and that the malfunction may have caused or contributed to a death or serious injury, then the manufacturer would need to submit an individual MDR for that event because it involves a reportable death or serious injury.

Manufacturers of devices in eligible product codes could continue submitting individual, 30-day malfunction reports in compliance with §§ 803.50 and 803.52 if they choose to do so. However, under the proposed program, those manufacturers would be permitted to 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.B and C of the document, unless one of the following individual reporting conditions applies:

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

The reporting requirements at § 803.53 would continue to apply to manufacturers participating in the proposed 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. Manufacturers participating in the proposed Voluntary Malfunction Summary Reporting Program must continue to submit reportable malfunction events that meet this standard as 5-day reports. In addition, after you submit a 5-day report, 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 90 days past the date that the remedial action has been resolved to FDA's satisfaction. Summary reporting of malfunctions may then resume on the regularly scheduled summary reporting cycle.

If FDA has made a written request for the submission of a 5-day report, you 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)).

Submission of reportable malfunctions associated with 5-day reports in this manner would allow FDA to monitor the time course and resolution of the issue presenting an unreasonable risk of substantial harm to the public health (see section II, summary reporting principle 4).

2. A Reportable Malfunction Is the Subject of an Ongoing Device Recall

When a device is the subject of a recall involving the correction or removal of a marketed product to address a malfunction, 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 to FDA until 90 days past the date the recall is terminated. Summary reporting may then resume on the regularly scheduled summary reporting cycle. This would allow FDA to monitor the frequency of reportable malfunctions associated with the recall and effectiveness of the recall strategy.

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 would provide written notice via letter to manufacturers of relevant devices that individual MDR submissions are necessary. FDA would provide further written notice when manufacturers of those devices may resume participation in summary malfunction reporting. If necessary to protect the public health, FDA may also revoke or modify in writing an exemption, variance, or alternative reporting requirement, pursuant to § 803.19(d).

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 proposed 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 would provide written notification to the device manufacturer to submit individual malfunction reports in compliance with §§ 803.50 and 803.52.

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.

B. Malfunction Reporting Summary Format

Manufacturers of devices in eligible product codes who participate in this proposed voluntary program would submit summary malfunction reports in the format described below.

1. Format Rationale

The proposed format for summary reporting largely adopts the format that was tested in the Pilot Program for Medical Device Reporting on Malfunctions.

FDA considered several approaches to summarizing information, given the summary reporting principles identified in section II. Since contextual information is needed to sufficiently understand reported malfunctions, FDA considered formats in which narrative text fields would provide sufficient context (see section II, summary reporting principle 1). In addition, summary text narratives without patient-specific information can often be shared publicly with fewer redactions, which may provide greater transparency of device-related malfunction information (see section II, summary reporting principle 3).

The QS regulation requires manufacturers to review, evaluate, and investigate any complaint that represents an event which must be reported to FDA under part 803, including reportable malfunction events (see § 820.198). In situations where several malfunction complaints are similar, FDA has found that many manufacturers aggregate information at the device model and device problem level in their investigation process. While this does not reduce the investigation requirements for manufacturers under part 803 or part 820 (see section II, summary reporting principle 5), aggregating malfunction reports by product and device problem would significantly reduce the number of reports. Likewise, FDA generally evaluates malfunction information at the product and device problem level, which streamlines the processing of malfunction reports and accelerates FDA's understanding of device issues. Therefore, FDA has determined that it would be mutually beneficial to organize summary malfunction

reporting information according to product and device problem.

A malfunction report may describe more than one device problem, and FDA believes that summary reporting information should not be duplicative (see section II, summary reporting principle 6). Therefore, FDA has developed a methodology to help ensure that summary malfunction reports are non-overlapping. Consider a hypothetical situation in which a manufacturer reports 100 malfunction events for a device, where 70 of those 100 reports represent device problem A, and 50 of those 100 reports represent device problem B. Reporting device problems A and B separately would create confusion regarding the total number of events received. Thus, in this example, device problem A, device problem B, and the subsequent overlap A+B, would be reported as three separate MDRs: A report describing 50 occurrences of device problem A, a report describing 30 occurrences of device problem B, and a report describing 20 occurrences involving both device problems A and B. In this way, the three separate MDRs would be mutually exclusive and unambiguous.

In consideration of the least burdensome means of reporting, FDA has developed a format that is compatible with the Form FDA 3500A (Ref. 3), 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). This would streamline the process of reporting (see section II, summary reporting principle 5). Because summary malfunction reports represent a grouping of malfunction events for a specific model of a device, the proposed 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 in section III.B.2., 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 would provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively.

2. Format Instructions

Separate summary malfunction reports would be submitted for each unique combination of device model and problem code(s). (See Appendix A for case examples of how to report (Ref. 5).) Each summary malfunction report would be required to include at least the following information collected on Form FDA 3500A and to 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, 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) 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(s) or model(s) that are the subject of the MDR.
- SECTION G.1: Contact Office (and Manufacturing Site 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 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 III.B.3).
- 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. 5).)
  - 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 your investigation for the reported malfunctions, including any followup actions taken, and any additional information that would be helpful in understanding how you 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 to you, the number of devices that were labeled ''for single use'' (if any), and the number of devices that were reprocessed and re-used (if any).

3. Combination Product Considerations

As noted above, FDA is considering how the alternative that would be granted under § 803.19 to permit summary malfunction reporting may apply to combination products that contain a device constituent part and seeks comment on this issue. FDA anticipates that modifications may be needed to the above format instructions for purposes of addressing combination product considerations. Additionally, if such combination products that received marketing authorization under a biological product or drug marketing application are included in the proposed alternative that would permit summary malfunction reporting, FDA anticipates that such reporting would be made through the Center for Drug Evaluation and Research's or CBER's electronic reporting system with adjustments made to the above format instructions for purposes of reporting through these systems. FDA seeks comment on these issues.

C. Submission Schedule and Logistics

Under the proposed program, manufacturers submitting summary malfunction reports would be required to use electronic reporting (Ref. 6) to submit those reports on a quarterly basis according to the schedule in table 1.

TABLE 1—SUMMARY MALFUNCTION REPORTING SCHEDULE

Reportable malfunctions 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 summary malfunction report would be required to 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.

With respect to combination products that include a device constituent part and that received marketing authorization under a biological product or drug marketing application, FDA seeks comment on whether a different reporting schedule would be more appropriate.

D. 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 summary format, as outlined in the MDUFA IV Commitment Letter (Ref. 4), in a manner that provides for effective monitoring of devices and is beneficial for FDA, industry, and the public. An important part of this proposed voluntary program is providing clarification to manufacturers regarding the product codes eligible for the program. FDA is currently in the process of evaluating device product codes to determine which ones should be eligible. The Agency is requesting comments on the product codes that should be eligible for this proposed Voluntary Malfunction Summary Reporting Program, including for combination products. FDA will consider the proposed list of eligible product codes submitted by industry along with any comments received on this proposal in determining the product codes that would be included in the proposed alternative granted to permit summary malfunction reporting.

Consistent with the MDUFA IV Commitment Letter (Ref. 4), when this proposed voluntary program is finalized through publication of a **Federal Register** document granting the alternative under § 803.19, FDA will identify on its website a list of device product codes that are eligible for the Voluntary Malfunction Summary Reporting Program as part of granting the alternative. Manufacturers that choose to participate in quarterly summary reporting through the proposed program would remain responsible for complying with applicable MDR requirements under part 803 (such as requirements to establish and maintain MDR event files under § 803.18) and QS requirements under part 820 (such as 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 would notify relevant manufacturers that they must submit individual reports and provide an explanation for that decision and 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.

E. Addition of Product Codes to the Program

FDA recognizes that new product codes will be created after the date that the Agency would grant the proposed alternative under § 803.19 to initiate the Voluntary Malfunction Summary Reporting Program. In general, FDA does not intend to consider devices under product codes in existence for less than 2 years to be eligible for the proposed program, unless the new product code was issued solely for administrative reasons. However, FDA proposes to 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 is eligible, then it would grant manufacturers of devices within that product code the same proposed alternative under § 803.19 for malfunction events associated with those devices. Manufacturers could also submit a request under § 803.19(b) 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 proposed alternative for malfunction events associated with those devices.

FDA believes that for many devices, the proposed quarterly summary reporting described above would be as effective as the current MDR reporting program for purposes of identifying and monitoring potential device safety concerns and device malfunctions. The proposed Voluntary Malfunction Summary Reporting Program would allow manufacturers to submit summary reports with event narratives that would help FDA more efficiently process malfunction reports and identify malfunction trends. In addition, FDA's determination of product code eligibility and the proposed conditions of participation in the program would require submission of individual 30-day or 5-day malfunction reports in circumstances where such reports are necessary to protect public health.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the

burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Reporting: Electronic Submission Requirements—21 CFR part 803

OMB Control Number 0910–0437—Revision

The information collection associated with part 803 is approved under OMB control number 0910–0437. We request revision of the information collection approval as described in this document.

FDA is announcing this proposed program for manufacturer reporting of certain device malfunction MDRs in summary form—the Voluntary Malfunction Summary Reporting Program. The proposed program would permit manufacturers of devices in certain product codes to report malfunctions for those devices on a quarterly basis and in a summary format (instead of reporting them as individual, 30-day reports), subject to certain conditions. Therefore, we have added a line item to the reporting burden table for the proposed Voluntary Malfunction Summary Reporting Program.

FDA believes that submission of voluntary summary reports in the format described in this document would provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively. The proposed Voluntary Malfunction Summary Reporting Program is meant to streamline the process of reporting malfunctions. It does not change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers. The proposed program would neither apply to importers or device user facilities, nor affect requirements under part 803 for importers or device user facilities. The proposed program would not apply to reportable death or serious injury events, as described above in section III.A. In addition, the reporting requirements at § 803.53, which require a 5-day report to be filed at the written request of FDA or 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, would continue to apply to manufacturers participating in the proposed program. The conditions of the proposed Voluntary Summary Malfunction Reporting Program would also require manufacturers to submit individual malfunction reports in certain circumstances (see section III.A.). These factors were considered in determining the revised burden estimates described below in table 2.

For the convenience of the reader, we have included below only the PRA line-items for the estimated annual reporting burden table from OMB control number 0910–0437 that we anticipate would be affected by the Voluntary Malfunction Summary Reporting Program. We have not included the information collection line-items that we do not anticipate would be affected by the proposed program and which we do not intend to revise at this time.

Activity/CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturer Reporting—§§ 803.50 through 803.53.	1,240	272.50	337,900	0.10 (6 minutes)	33,790
Voluntary Malfunction Summary Reporting Program.	1,240	54.47	67,546	0.10 (6 minutes)	6,755
Supplemental Reports—§ 803.56	1,050	128.71	135,148	0.10 (6 minutes)	13,515

[1] There is no change to the capital costs or operating and maintenance costs associated with this revision of the collection of information.

We believe the availability of the summary reporting option for manufacturers of certain devices would cause a decrease in the number of individual manufacturer reports for malfunctions submitted under §§ 803.50 and 803.52. We have, therefore, revised the estimated number of responses for Manufacturer Reporting—§§ 803.50 through 803.53 accordingly. As explained above in section III.D., the Agency does not yet have a final list of the product codes that would be eligible for the proposed Voluntary Malfunction Summary Reporting Program, and FDA does not anticipate that all device product codes would be included in the alternative granted to permit summary, quarterly malfunction reporting. However, based on the scope and conditions of the proposed program, the interest industry has expressed in summary malfunction reporting, and our experience with MDR reporting, FDA estimates that approximately 10 percent of malfunction reports would continue to be submitted as individual reports after implementation of the proposed program. Approximately 67 percent of the manufacturer reports received under §§ 803.50 through 803.53 are malfunction reports (577,316 of the 857,484 total annual responses received in 2016). We therefore estimate the revised Responses per Respondent for ''Manufacturer Reporting—§§ 803.50 through 803.53'' to be 272.50.

We estimate that a summary malfunction report would take approximately the same amount of time to prepare as an individual malfunction report. As discussed in section I of this document, FDA's Pilot Program for Medical Device Reporting on Malfunctions showed an 87 percent reduction in the volume of reporting for malfunction reports with use of malfunction summary reporting. Assuming 90 percent of malfunction reports are submitted in summary reports, we estimate that manufacturers would submit an average of 54.47 summary reports annually under this proposed program.

Based on our experience with supplemental reporting, we estimate that, at most, the number of supplemental reports would be approximately one third of the total number of individual reports and summary reports submitted annually. We, therefore, estimate the revised Responses per Respondent for ''Supplemental Reports—§ 803.56'' to be 128.71.

We will update these estimates as appropriate based on comments received on this proposed information collection and the list of eligible device product codes that FDA develops.

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 21 CFR 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 21 CFR part 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 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.

V. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) 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. Food and Drug Administration, ''Medical Device Reporting—Alternative Summary Reporting (ASR) Program, Guidance for Industry,'' available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072102.pdf.*

2. Food and Drug Administration, Event Problem Codes, available at *https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/reportingadverseevents/mdradverseeventcodes/default.htm.*

3. Food and Drug Administration, FDA Form 3500A, available at *https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm048334.pdf.*

4. MDUFA IV Commitment Letter, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*

5. Appendix A, ''Case Examples of Summary Malfunction Reporting,'' available in Docket No. FDA–2017–N–6730.

6. 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: *http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm.*

Dated: December 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27650 Filed 12–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Parts 478 and 479

[Docket No. 2017R–22]

RIN 1140–AA52

Application of the Definition of Machinegun to ''Bump Fire'' Stocks and Other Similar Devices

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF).

ACTION: Advance notice of proposed rulemaking; request for comments.

SUMMARY: The Department of Justice anticipates issuing a Notice of Proposed Rulemaking (NPRM) that would interpret the statutory definition of ''machinegun'' in the National Firearms Act of 1934 and Gun Control Act of 1968 to clarify whether certain devices, commonly known as ''bump fire'' stocks, fall within that definition. Before doing so, the Department and ATF need to gather information and comments from the public and industry regarding the nature and scope of the market for these devices.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before January 25, 2018. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after Midnight Eastern Standard Time on the last day of the comment period.

ADDRESSES: You may submit comments, identified by docket number (2017R–22), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Fax:* (202) 648–9741.
- *Mail:* Vivian Chu, Mailstop 6N–518, Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, 99 New York Ave. NE, Washington DC 20226. *ATTN: 2017R–22.*

Instructions: All submissions received must include the agency name and docket number for this advance notice of proposed rulemaking (ANRPM). All comments received will be posted without change to the Federal eRulemaking portal, *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' section of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Vivian Chu, Office of Regulatory Affairs, Enforcement Programs Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Ave. NE, Washington DC 20226; telephone: (202) 648–7070.

SUPPLEMENTARY INFORMATION:

I. Background

The Attorney General is responsible for enforcing the Gun Control Act of 1968 (GCA), as amended, 18 U.S.C. 921 *et seq.,* and the National Firearms Act of 1934 (NFA), as amended, 26 U.S.C. 5841 *et seq.*[1] The Attorney General has delegated the responsibility for administering and enforcing these laws to the Director of ATF subject to the direction of the Attorney General and the Deputy Attorney General. *See* 28 CFR 0.130. Regulations in 27 CFR parts 478 and 479 implement the GCA and NFA.

The NFA defines ''machinegun'' as any weapon which: ''shoots, is designed to shoot, or can be readily restored to shoot automatically more than one shot, without manual reloading, by a single function of the trigger.'' The term also includes ''the frame or receiver of any such weapon, any part designed and intended solely and exclusively, or combination of parts designed and intended, for use in converting a weapon into a machinegun, and any

[1] NFA provisions still refer to the ''Secretary of the Treasury.'' However, the Homeland Security Act of 2002, Public Law 107–296 (2002), transferred the functions of ATF from the Department of the Treasury to the Department of Justice, under the general authority of the Attorney General. 26 U.S.C. 7801(a)(2); 28 U.S.C. 599A(c)(1). Thus, this document refers to the Attorney General.