obtaining an order under section 911(g)(1) of the FD&C Act;

- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;
- The magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and
- Issuance of the exposure modification order is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that the MRTPAs for the following products submitted by Philip Morris Products S.A. have been filed and are being made available for public comment:

- MR0000254.PD1: IQOS 2.4 System Holder and Charger
- MR0000254.PD5: Marlboro Amber HeatSticks
- MR0000254.PD6: Marlboro Green Menthol HeatSticks
- MR0000254.PD7: Marlboro Blue Menthol HeatSticks

The applicant is seeking renewal of the authorization to market the IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks,[1] Marlboro Green Menthol HeatSticks [2] and Marlboro Blue Menthol HeatSticks,[3] products that previously received authorization under section 911(g)(2) of the FD&C Act [4] to be marketed as modified risk tobacco products with reduced exposure claims. For purposes of premarket review, FDA has identified these tobacco products as HTPs. HTPs meet the definition of a cigarette, but the tobacco is heated and not combusted (products that do not exceed 350 °C). The applicant is including information from the previous MRTPAs by cross-reference.

FDA will post the application documents, including any amendments, to its website for the MRTPAs (see section II) for public comment on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 180 days after the date of this notice and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of information in the MRTPA that has not already been available for public comment as part of the previously authorized MRTPAs for the IQOS system.

FDA will notify the public about the availability of additional application documents and comment period closing date via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. To receive email alerts, visit FDA's email subscription service management website (*https://www.fda.gov/about-fda/contact-fda/get-email-updates*), provide an email address, scroll down to the ''Tobacco'' heading, select ''Modified Risk Tobacco Product Application Update'', and click ''Submit''. FDA does not intend to issue additional notices in the **Federal Register** regarding the availability of additional application documents, including amendments, or the comment period for this MRTPA. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

[1] Product name was previously Marlboro Heatsticks.

[2] Product name was previously Marlboro Smooth Menthol Heatsticks.

[3] Product name was previously Marlboro Fresh Menthol Heatsticks.

[4] The notice of availability for the IQOS MRTPAs that received modified risk granted orders appeared in the **Federal Register** of June 15, 2017 (82 FR 27487), and the docket containing notices and public comments, FDA–2017–D–3001, is accessible at: *https://www.regulations.gov/docket/FDA-2017-D-3001.*

II. Electronic Access

Persons with access to the internet may obtain the document(s) *https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications.*

Dated: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10054 Filed 5–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3741]

Remanufacturing of Medical Devices; Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Remanufacturing of Medical Devices.'' This final guidance is intended to help clarify whether activities performed on devices are likely ''remanufacturing.'' This final guidance also clarifies existing regulatory requirements for remanufacturers and includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–N–3741 for ''Remanufacturing of Medical Devices.'' Received comments 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Remanufacturing of Medical Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Katelyn Bittleman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4250, Silver Spring, MD 20993–0002, 240–402–1478; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. However, there is a lack of clarity regarding the distinction between ''servicing'' and ''remanufacturing'' activities. FDA has been working to promote clarity on the distinction between ''servicing'' and ''remanufacturing.''

FDA opened a docket for public comment (81 FR 11477) and held a public workshop (81 FR 46694) in 2016. The Food and Drug Administration Reauthorization Act (FDARA) became law on August 18, 2017. Section 710 of FDARA charged the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to issue a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing. In May 2018, FDA published on its website the report entitled ''FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices'' (*https://www.fda.gov/media/113431/download*). One conclusion of the report stated ''a majority of comments, complaints, and adverse event reports alleging that inadequate 'servicing' caused or contributed to clinical adverse events and deaths actually pertain to 'remanufacturing' and not 'servicing,' '' and FDA committed to issue guidance that clarifies the difference between servicing and remanufacturing activities. In December 2018, FDA issued a white paper entitled ''Evaluating Whether Activities are Servicing or Remanufacturing'' (*https://www.fda.gov/media/117238/download*), opened a public docket (FDA–2018–N–3741), and held a public workshop (*https://wayback.archive-it.org/7993/20201222125933/https:/www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-medical-device-servicing-and-remanufacturing-activities-december-10-11-2018-12102018*) to facilitate public discussion on the distinction between servicing and remanufacturing. The white paper described FDA's initial thoughts about guiding principles, provided a flowchart with accompanying text for understanding the distinctions, and contained a complementary approach for software, as well as considerations for labeling and examples utilizing the flowchart. FDA also included targeted questions throughout the white paper on which the Agency sought feedback. FDA

considered the comments from the public docket and discussions during the public workshop in developing the draft guidance. A notice of availability of the draft guidance appeared in the **Federal Register** of June 24, 2021 (86 FR 33305).

FDA focuses this guidance on activities that are likely remanufacturing—processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use (see 21 CFR 820.3(w)). The determination of whether the activities an entity performs are remanufacturing affects the applicability and enforcement of regulatory requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. FDA has consistently enforced requirements under the FD&C Act and its implementing regulations on entities engaged in remanufacturing, including but not limited to registration and listing, adverse event reporting, the Quality System regulation, and marketing submissions.

FDA considered comments received and revised the guidance as appropriate. In this final guidance, FDA provided additional contextual examples of activities throughout Section VI.B to provide further clarity when determining whether activities remanufacture a device. FDA clarified the applicability of the guidance to original equipment manufacturers (OEMs) and external entities on behalf of OEMs. FDA also added Section VIII ''Regulatory Requirements and Considerations for Remanufacturers'' to the guidance clarifying and outlining certain existing regulatory requirements that apply to remanufacturers.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Remanufacturing of Medical Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Remanufacturing of Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00017048 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or FDA form	Topic	OMB control No.
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910–0485
803	Medical Device Reporting	0910–0437
Form FDA 3670	Adverse event reports/MedSun program	0910–0471
806	Medical Devices; Reports of Corrections and Removals	0910–0359
810	Medical Device Recall Authority	0910–0432
820	Current Good Manufacturing Practice; Quality System Regulation	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910–0625
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
860, subpart D	De Novo classification process	0910–0844
812	Investigational Device Exemption	0910–0078
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
1000 through 1040	Electronic Products Requirements	0910–0025

Dated: May 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10230 Filed 5–9–24; 8:45 am]

BILLING CODE 4164–01–P