3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Programs of All-Inclusive Care for the Elderly (PACE) PACE Quality Data Monitoring and Reporting; *Use:* The Programs of All-Inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits. To be eligible to enroll in PACE, an individual must: be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community with assistance from PACE.

PACE organizations are responsible for providing all required Medicare and Medicaid covered services, and any other service that the interdisciplinary team (IDT) determines necessary to improve and maintain a participant's overall health condition (42 CFR 460.92). POs must also comply with the quality monitoring and reporting requirements outlined in §§ 460.140, 460.200(b)(1), 460.200(c) and 460.202. POs are also required to report certain unusual incidents to other Federal and State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR 460.136(a)(5)). *Form Number:* CMS–10525 (OMB control number: 0938–1264); *Frequency:* Occasion; *Affected Public:* Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 152; *Total Annual Responses:* 1,279; *Total Annual Hours:* 1,471. (For policy questions regarding this collection contact Donna Williamson at 410 786 4647.)

Dated: November 28, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–26444 Filed 11–30–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1051]

Modified Risk Tobacco Product Application: Renewal Applications for General Snus Smokeless Tobacco Products Submitted by Swedish Match U.S.A., Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity to provide public comment on modified risk tobacco product applications (MRTPAs). The applications are for renewal of existing modified risk tobacco product (MRTP) orders for *General Snus* smokeless tobacco products submitted by Swedish Match U.S.A., Inc.

DATES: Electronic or written comments on the application may be submitted beginning December 1, 2023. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments 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–2014–N–1051 for ''Modified Risk Tobacco Product Applications: Renewal applications for *General Snus* smokeless tobacco products submitted by Swedish Match U.S.A., Inc.'' 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 the background documents or 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.

FOR FURTHER INFORMATION CONTACT: Dhanya John or Adrian Mixon, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of MRTPs. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (g)(2). The applicant, Swedish Match U.S.A., Inc., is seeking a renewal of the order under section 911(g)(1) of the FD&C Act.

FDA may issue an order under Section 911(g)(1) of the FD&C Act, if FDA has determined that the applicant has demonstrated that the proposed MRTP, as it is actually used by consumers, will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- 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 renewal MRTPAs submitted by Swedish Match U.S.A. Inc. for the following products (identified by FDA Submission Tracking Numbers (STN) (MR0000256.PD1—MR0000256.PD9)) have been filed and are being made available for public comment:

- MR0000256.PD1: General Loose
- MR0000256.PD2: General Dry Mint Portion Original Mini
- MR0000256.PD3: General Portion Original Large
- MR0000256.PD4: General Classic Blend Portion White Large-12 ct
- MR0000256.PD5: General Mint Portion White Large
- MR0000256.PD7: General Nordic Mint Portion White Large- 12 ct
- MR0000256.PD8: General Portion White Large
- MR0000256.PD9: General Wintergreen Portion White Large

The applicant is seeking renewal of the authorization to market *General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large—12ct, General Mint Portion White Large, General Nordic Mint Portion White Large—12ct, General Portion White Large, and General Wintergreen Portion White Large Smokeless Tobacco Products (category)/ Loose Snus and Portioned Snus (subcategories)* as MRTPs under section 911(g)(1) of the FD&C Act.[1] These products previously received such authorization in October 2019, and 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 the applications being posted.

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 MRTPAs (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''. 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).

II. Electronic Access

Persons with access to the internet may obtain the document(s) at *https://www.fda.gov/tobacco-products/advertising-and-promotion/swedish-match-usa-inc-mrtp-applications.*

Dated: November 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26498 Filed 11–30–23; 8:45 am]

BILLING CODE 4164–01–P

[1] The notice of availability for the General Snus MRTPAs that received a modified risk granted order appeared in the **Federal Register** on August 27, 2014 (79 FR 51183) and the docket containing notices and public comments, FDA–2014–N–1051, is accessible at: *https://www.regulations.gov/.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3007]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act and Associated Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.