''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.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 2, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0776. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Associated Fees Under Section 744K

OMB Control Number 0910–0776—Extension

This information collection helps to support implementation of section 503B of the FD&C Act (21 U.S.C. 353b) and the assessment and remission of user fees under section 744K of the FD&C Act (21 U.S.C. 379j–62).

A. Registration

Under section 503B of the FD&C Act a facility that compounds drugs may elect to register with FDA as an outsourcing facility. Upon electing to do so, outsourcing facilities must register annually between October 1 and December 31, providing information that includes its name, place of business, a unique facility identifier, and a point of contact's email address and phone number. The outsourcing facility must also indicate: (1) whether it intends to compound, within the next calendar year, a drug that appears on our drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) and (2) whether it compounds from bulk drug substances and, if so, whether it compounds sterile or nonsterile drugs from bulk drug substances. Registered outsourcing facilities must submit a drug product report upon initial registration under section 503B of the FD&C Act and twice each year in June and December for drug products produced during the previous 6-month period. We require this data be submitted electronically, unless a waiver is granted, in structured product labeling (SPL) format.

Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA-approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the requirements for drug supply chain security in section 582 of the FD&C Act (21 U.S.C. 360eee–1) if the requirements in section 503B of the FD&C Act have been met. We provide general information and resources on our website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding,* including a list of currently registered outsourcing facilities as required under section 503B of the FD&C Act.

B. Registration Fees

Upon registration, and in accordance with sections 503B and 744K of the FD&C Act, facilities are assessed an establishment fee and receive an annual invoice from FDA with instructions for remitting payment. Until payment is made for each given fiscal year (FY), an establishment is not considered to be registered as an outsourcing facility. In accordance with section 744K of the FD&C Act, certain outsourcing facilities may qualify for a small business reduction in the amount of the annual establishment fee. To qualify for this reduction, an outsourcing facility must submit a written request to FDA certifying that the entity meets the requirements for the reduction. For each FY a firm seeks to qualify as a small business and receive the fee reduction, it must submit to FDA a written request by April 30 of the preceding FY. For example, an outsourcing facility must have submitted a written request for the small business reduction by April 30, 2023, to qualify for a reduction in the FY 2024 annual establishment fee.

Section 744K of the FD&C Act also requires an outsourcing facility to submit written requests for a small business reduction in a specified format: Form FDA 3908 entitled ''Outsourcing Facilities for Human Drug Compounding: Small Business Establishment Fee Reduction Request.'' The completed form should be submitted via email to *CDERCollections@fda.hhs.gov.* Form FDA 3908 is available from our website at: *https://www.fda.gov/media/90740/download.* In response to the submission of a small business reduction request, FDA will send a notification letter of its decision and recommends that applicants retain the notification.

C. Reinspection Fees

In accordance with section 503B of the FD&C Act, outsourcing facilities are subject to inspection and, in accordance with section 744K of the FD&C Act, subject to reinspection fees. A reinspection fee will be incurred for each reinspection and is intended to reimburse FDA when a particular outsourcing facility requires reinspection because of noncompliance identified during a previous inspection. After a reinspection is conducted, FDA will send an invoice to the email address indicated in the facility's registration file. The invoice contains instructions for remitting the reinspection fee. For further information on human drug compounding outsourcing facility fees, please visit our website at *https://www.fda.gov/industry/fda-user-fee-programs/human-drug-compounding-outsourcing-facility-fees.*

D. Dispute Resolution

Agency regulations under § 10.75 (21 CFR 10.75) provide for internal Agency review of decisions. Accordingly, an outsourcing facility may request reconsideration of an FDA decision related to the fee provisions of section 744K of the FD&C Act. Requests for reconsideration should include the facility's rationale for its position that FDA's decision was in error and include any additional information that is relevant to the outsourcing facility's assertion. The denial of a request for reconsideration may be appealed by submitting a written request to FDA, consistent with § 10.75.

To assist respondents with the information collection provisions, we have developed Agency guidance documents. The guidance document entitled ''Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act (November 2014)'' describes the process for electronic submission of

establishment registration information for outsourcing facilities and provides information on how to obtain a waiver from submitting registration information electronically. The guidance document entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act (November 2014)'' (Fees for Human Drug Compounding Outsourcing Facilities guidance) describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees. The guidance documents were issued consistent with our good guidance practice regulations (21 CFR 10.115), which provide for public comment at any time, and are available on our website at *https://www.fda.gov/media/87570/download* and *https://www.fda.gov/media/136683/download,* respectively.

All requests for dispute resolution should be sent via email to the Division of User Fee Management and Budget Formulation at *CDERCollections@fda.hhs.gov.* If an outsourcing facility does not have email access, it can mail a request to FDA via the carrier of its choice. For the most updated physical mailing address, visit this website: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm382846.htm.*

In the **Federal Register** of August 15, 2023 (88 FR 55464), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section; guidance or associated FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using the SPL Format; 207.61; Section III. of the ''eDRLS'' [2] guidance.	79	1	79	4.5	355
Waiver Request from Electronic Submission of Registration Information; 207.65; Section VI. of the ''eDRLS'' [2] guidance.	1	1	1	1	1
Remission of Annual Establishment Fee from FDA Invoice; Section E.1. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	76	1	76	0.5 (30 minutes)	38
Request for Small Business Reduction (Form FDA 3908).	18	1	18	25	450
Reinspection Fees; Section C. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	12	1	12	0.5 (30 minutes)	6
Reconsideration Requests; Section V.B.1. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	1	1	1	1	1
Appeal of Reconsideration Denials; Section V.B.2. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	1	1	1	1	1
Total			188		852

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing'' (May 2009; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-drug-establishment-registration-and-drug-listing*).

We estimate 79 respondents annually will submit outsourcing facility registrations using the SPL format as specified in Agency guidance and assume each registration will require 4.5 hours to prepare and complete. We expect no more than one waiver request from the electronic submission requirement annually and assume each waiver request will require 1 hour to prepare and submit. We estimate each of the 76 registrants will remit annual establishment fees and assume this task requires 30 minutes per respondent. We estimate that 18 of those respondents will request a small business reduction in the amount of the annual establishment fee using Form FDA 3908.

We estimate 12 outsourcing facilities annually will remit reinspection fees and assume this will require 30 minutes. We also estimate that we will receive one request for reconsideration and one appeal of a denial of a request for reconsideration and assume 1 hour per respondent for this activity.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Retention of Small Business Designation Notification Letter.	18	1	18	0.5 (30 minutes)	9

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that annually 18 outsourcing facilities will maintain a copy of their small business designation letter and that maintaining each record will require 30 minutes. These estimates reflect a slight increase in the number of annual registrations, but a decrease in reinspection fee submissions.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26445 Filed 11–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0955–0018]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 30, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV*.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0955–0018–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.

Type of Collection: Extension.

OMB No.: 0955–0018.

Abstract: The Department of Health and Human Services, Office of the Secretary, Office of the National Coordinator for Health IT Office of Policy, is requesting an approval by OMB on an extension request which pertains to a records and information retention requirement found at 45 CFR 170.402(b)(1). The purpose and use of this records and information retention requirement is to verify, as necessary, health IT developer compliance with the ONC Health IT Certification Program (Program) requirements, including certification criteria and Conditions and Maintenance of Certification. Specifically, a health IT developer must, for a period of 10 years beginning from the date each of a developer's health IT is first certified under the Program, retain all records and information necessary that demonstrate initial and ongoing compliance with the requirements of the Program.

ANNUALIZED BURDEN HOUR TABLE

Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Health IT Developers	435	1	104	45,240
Total	435			45,240

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2023–26477 Filed 11–30–23; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report Office of the Director (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To submit comments in writing or request more information on the proposed collection, contact: Jane J. Na, Director, Division of Assurances, Office of Laboratory Animal Welfare, NIH, call (301) 496–7163 or email your request to *olawdoa@mail.nih.gov.* Formal requests for information collection forms must be requested via email to *olawdoa@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on December 15, 2022, Vol. 87, No. 240 page 76631–76632 (87 FR 76631) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of the Director (OD), National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number.