found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14929 Filed 7–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 August 12, 2022.

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 0910–0732. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St. North Bethesda, MD 20852, 301–796–8867, *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.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0732—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (final deeming rule) (81 FR 28974).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as a harmful and potentially harmful constituent (HPHC) to health by FDA. Reports must be by brand and by quantity in each brand and subbrand. We note that for cigarettes, smokeless tobacco, cigarette filler, and RYO tobacco products, this initial reporting was completed in 2012.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) of the FD&C Act at least 90 days prior to introducing the product into interstate commerce.

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011, revised guidance issued August 2016). The guidance is available on the internet at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/harmful-and-potentially-harmful-constituents-tobacco-products-used-section-904e-federal-food-drug.* The current established list of HPHCs also is available on the internet at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list* (77 FR 20034, April 3, 2012).

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in certain tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, Forms FDA 3787a-j, for cigarettes, smokeless tobacco products, and RYO tobacco products, respectively, in both paper and electronic formats, are available. Additionally, FDA is developing forms to facilitate the submission of HPHC information for the deemed tobacco products. We intend to model these forms on the current HPHC reporting forms (*i.e.,* Forms FDA 3787a–j). A proposed information collection for deemed products will be published in a separate **Federal Register** notice, and we will solicit comments on that collection at that time.

Manufacturers or importers, or their agents, may submit HPHC information either electronically or in paper format. The FDA eSubmitter tool, available at *https://www.fda.gov/industry/fda-*

esubmitter/using-esubmitter-prepare-tobacco-product-submissions, provides electronic forms to streamline the data entry and submission process for reporting HPHCs for cigarettes, smokeless tobacco products, and RYO tobacco products. Users of eSubmitter may populate an FDA-created Excel file and import data into eSubmitter. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for completing and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information.

In the **Federal Register** of February 7, 2022 (87 FR 6869), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We have adjusted estimates in the number of respondents and responses per respondent from the 60-day **Federal Register** notice to better align with previous assessments that utilized the number of entities. The number of respondents now reflects the estimated number of cigarettes, RYO, and smokeless tobacco product manufacturers, importers, or their agents. The burden totals were unchanged from the 60-day notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	48	7.92	380	1.82	692
RYO	43	0.44	19	0.43	8
Smokeless	34	0.74	25	0.63	16
Total					716
2. Testing of HPHC Quantities in Products					
Cigarette Filler and RYO	43	0.44	19	9.42	179
Smokeless	34	0.74	25	12.06	302
Total					481
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	48	7.92	380	23.64	8,983
Cigarette: Health Canada Regimen	48	7.92	380	23.64	8,983
Total					17,996
Total Section 904(c)(1) Reporting Burden Hours					19,193

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

The burden estimate for this collection of information includes the time it will take to read the instructions, test the products, and prepare the HPHC report. In arriving at this burden estimate, FDA estimated the number of tobacco products to be reported under the requirements of section 904(c)(1) of the FD&C Act annually to FDA.

Section 1 of Table 1 estimates that 125 respondents (48 cigarette, 43 RYO, and 34 smokeless tobacco product manufacturers, importers, or their agents) will submit 424 HPHC reports annually. Each respondent must report their product information to FDA under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce for all new products. We have adjusted information in the number of respondents and responses per respondent from the 60-day **Federal Register** notice to better align with previous assessments. The number of respondents now reflects the estimated number of cigarettes, RYO, and smokeless tobacco product manufacturers, importers, or their agents. This section addresses the time required to report their company information to FDA using the electronic portal or paper forms.

The company information reported includes company name; mailing address; telephone and fax numbers; FDA Establishment Identifier number; Data Universal Numbering System number; and point of contact name, mailing address, and telephone and fax numbers, as applicable. It also addresses the time required for manufacturers and importers to report their product information by entering certain testing information into the electronic or paper forms.

The product information includes brand and subbrand name; unique product identification number; type of product identification number; product category and subcategory; and mean weight and standard deviation of tobacco in product.

We estimate that the burden to enter both the company and product information is no more than 1.82 hours per response for cigarettes, 0.43 hours per response for RYO, and 0.63 hours per response for smokeless tobacco products regardless of whether the paper or electronic Form FDA series 3787 is used. The time to report per tobacco product types varies because the number of HPHCs varies by tobacco product category. The total hours estimated for this section is 716.

The estimated total annual responses under section 904(c)(1) are based on FDA's experience and the past 4 years of tobacco products receiving marketing authorizations from FDA, and the requirements to submit HPHC data

under this provision of the FD&C Act for statutorily regulated products.

Section 2 of Table 1 estimates that 77 respondents (43 cigarette filler and RYO tobacco and 34 smokeless manufacturers, importers, or their agents) will test quantities of HPHCs in an average of 44 products annually. This section addresses the time required for manufacturers and importers (or their agents) who must test HPHC quantities in products. The burden estimates include the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The total expected burden for this section is 481 hours.

Section 3 of Table 1 addresses the time required for manufacturers and importers to test quantities for HPHCs in cigarette smoke. The burden estimates include: the burden to test the number of replicate measurements; test date range; manufacture date range; extraction method; separation method; detection method; and mean quantity and standard deviation of HPHCs and includes the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The annual burden reflects our estimate of the time it takes to test the tobacco products (*i.e.,* carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to both the ISO and Health Canada smoking regimens. The total expected burden is 17,996 hours for this section.

The total estimated burden for this information collection is expected to be 19,193 hours and 424 annual responses. Our estimated burden for the information collection reflects an overall increase of 354 annual responses and a corresponding increase of 16,677 hours. We attribute this adjustment to updated methodology in which the current estimates are derived from historical statutory tobacco product applications submitted and authorized by FDA in the past 4 years as: (1) manufacturers and importers (or their agents) of authorized products are required to submit HPHC reports at least 90 days prior to delivery for introduction into interstate commerce for all new products; and (2) initial reporting under section 904(a)(3) of the FD&C Act for statutory products was completed in 2012.

Dated: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14931 Filed 7–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0002]

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 September 12, 2022.

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

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0945–0002–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@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: Civil Rights and Conscience Complaint and Health Information Privacy & Security Complaint

Type of Collection: Office of Civil Rights (OCR)—Extension

OMB No. 0945–0002

Abstract:

ESTIMATED ANNUALIZED BURDEN TABLE

Written forms/electronic forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Civil Rights/Conscience Discrimination Complaint.	Individuals or households, Not-for-profit institutions.	15,446	1	45/60	11,585
Health Information Privacy Complaint.	Individuals or households, Not-for-profit institutions.	30,392	1	45/60	22,794
Total		45,838		45/60	34,379

Sherrette A. Funn,

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

[FR Doc. 2022–14869 Filed 7–12–22; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the