TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request					
§ 1107.1(c)—Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
Total Hours (§ 1107.1(c))					450
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)					
Abbreviated report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	1,217	1	1,217	2	2,434
Total Hours (section 905(j)(1)(A)(ii)) of the FD&C Act					2,434
Total Hours Exemptions From Substantial Equivalence Requirements					22,372

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

FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours per response.

FDA further estimates that we will receive 150 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 450 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 2 hours to prepare, as required by section 905(j)(1)(A)(ii) of the FD&C Act, for a total of 2,434 hours.

Our estimated burden for the information collection reflects an overall decrease of 1,499 hours and 94 respondents. The estimates reflect a decrease of 1,217 hours to account for a reduction in average response time for preparing an abbreviated report. FDA provides a recommended format for applicants in the exemption order letter that significantly reduces the burden hours for preparing the abbreviated report. The estimates also reflect a decrease of 94 responses for submissions requiring additional information in support of the initial exemption request, which resulted in a decrease of 282 hours. We attribute this adjustment to the number of submissions we received over the last few years. Therefore, FDA now estimates the burden for exemptions from substantial equivalence requirements is 22,372 hours.

Dated: February 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03992 Filed 2–24–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0377]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the tobacco health document submission.

DATES: Submit either electronic or written comments on the collection of information by April 26, 2022.

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 April 26, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 26, 2022. 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–2013–N–0377 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission.'' 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, 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.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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 extension 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.

With respect to the following collection of information, FDA invites comments on these 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.

Tobacco Health Document Submission

OMB Control Number 0910–0654—Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Additionally, section 101 of the Tobacco Control Act amended the FD&C Act by adding, among other things, new section 904(a)(4) (21 U.S.C. 387d(a)(4)).

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives'' (herein referred to as ''tobacco health documents'').

The guidance document ''Health Document Submission Requirements for Tobacco Products (Revised)'' (2017) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-health-document-submission*) requests health documents based on statutory requirements and compliance dates.[1] As indicated in the guidance, all manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act). However, FDA generally does not intend to enforce the requirement at this time with respect to

[1] FDA announced the availability of a guidance on this collection in the **Federal Register** on April 20, 2010 (75 FR 20606) (revised December 5, 2016 (81 FR 87565)).

all such health documents, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, are provided at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

FDA is planning revisions to the guidance to reflect that the deemed tobacco product compliance period has passed. Additional revisions include clarifying and editorial changes to promote a better understanding of FDA's interpretation of the ''health, toxicological, behavioral, or physiologic'' phrase, examples of health, toxicological, behavioral, or physiologic effects documents, and minor updates to the metadata list.

FDA has been collecting the information submitted pursuant to section 904(a)(4) of the FD&C Act through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. On both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification
- Submitter type, company name, address, country, company headquarters Dun and Bradstreet D–U–N–S number, and FDA assigned Facility Establishment Identifier (FEI) number
- Submitter point of contact
- Contact name, title, position title, email, telephone, and Fax
- Submission format and contents (as applicable)
- Electronic documents: Media type, media quantity, size of submission, quantity of documents, file type, and file software
- Paper documents: Quantity of documents, quantity of volumes, and quantity of boxes
- Whether or not a submission is being provided
- Confirmation statement
- Identification and signature of submitter including name, company name, address, position title, email, telephone, and Fax
- Document categorization (as applicable): Relationship of the document or set of documents to the following:
  - Health, behavioral, toxicological, or physiological effects
  - Uniquely identified current or future tobacco product(s)
  - Category of current or future tobacco product(s)
  - Specific ingredient(s), constituent(s), component(s), or additive(s)
  - Class of ingredient(s), constituent(s), component(s), or additive(s)
- Document readability and accessibility: Keywords; glossary or explanation of any abbreviations, jargon, or internal (*e.g.,* code) names; special instructions for loading or compiling submission.
- Document metadata: Date document was created, document author(s), document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, Bates number ranges for documents attached to a submitted email, document type, and whether the document is present in the University of California San Francisco's Truth Tobacco Documents database.

You may access the electronic form and paper form on our website, at *https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal* and *https://www.fda.gov/media/78652/download,* respectively. In addition to the electronic and paper forms, FDA issued the guidance on this collection to assist persons making tobacco health document submissions. For further assistance, FDA is providing a technical guide, embedded hints, and a web tutorial on the electronic portal.

FDA issued a final rule to deem products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act on May 10, 2016 (81 FR 28973), which became effective on August 8, 2016. The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extended the Agency's ''tobacco product'' authorities to all other categories of products that meet the statutory definition of ''tobacco product'' in the FD&C Act, except accessories of such deemed tobacco products.

For tobacco products subject to the deeming rule, FDA understands ''current or future tobacco products'' to refer to products commercially distributed on or after August 8, 2016, or products in any stage of research or development at any time after August 8, 2016, including experimental products and developmental products intended for introduction into the market for consumer use. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco, FDA understands ''current or future tobacco products'' to refer to products commercially distributed on or after June 23, 2009, or products in any stage of research or development at any time after June 23, 2009, including experimental products and developmental products intended for introduction into the market for consumer use.

In the guidance on this collection, FDA indicated our intent to enforce the requirement at this time with respect to all such health documents relating to the deemed tobacco products, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, were submitted by February 8, 2017, or in the case of small-scale deemed tobacco product manufacturers (small-scale manufacturers), by November 8, 2017 (81 FR 28973 at 29008 and 29009). Additionally, FDA extended the compliance deadlines by an additional 6 months for small-scale manufacturers in the areas impacted by natural disasters to May 8, 2018. Thereafter, FDA's compliance plan requested deemed manufacturers provide tobacco health document submissions from the specified period, at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

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
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600

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

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers, or agents thereof, would have health documents to submit. We anticipate documents will be submitted on an annual basis for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

Based on a review of the information collection of our current OMB approval, we have made no adjustments to our burden estimate.

Dated: February 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03994 Filed 2–24–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 Advisory Council for Human Genome Research.

The meeting will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from *https://www.genome.gov/about-nhgri/Institute-Advisors/National-Advisory-Council-for-Human-Genome-Research*. Any member of the public may submit written comments no later than 15 days after the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: May 16–17, 2022.

Closed: May 16, 2022, 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700–B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Virtual Meeting).

Open: May 16, 2022, 11:30 a.m. to 5:00 p.m.

Agenda: Report of Institute Director and Institute Staff.

Place: National Human Genome Research Institute, National Institutes of Health, 6700–B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Virtual Meeting).

Closed: May 17, 2022, 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700–B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700–B Rockledge Drive, Suite 1100, (301) 402–0838, *pozzattr@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: February 18, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04002 Filed 2–24–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Exercise and Alzheimer's Disease.

Date: March 22, 2022.

Time: 11:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institutes of Health, National Institute on Aging, Bethesda, MD 20814, (301) 827–3101, *dario.dieguez@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)