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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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 for this collection of information is estimated to be 19,193 hours. 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 424 respondents (380 cigarettes receiving authorizations, 19 RYO tobacco receiving authorizations, 25 smokeless receiving authorizations) will submit 424 HPHC reports annually. Each respondent represents a statutory tobacco product that receives authorization from FDA for which manufacturers and importers (or their agents), 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. This section addresses the time required to report their company information to FDA through the use of 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 number of responses under section 904(c)(1) of the FD&C Act is based on FDA's experience, the past 4 years of tobacco products receiving marketing authorizations from FDA, and actual responses to FDA under this provision of the FD&C Act for statutorily regulated products.

Section 2 of table 1 estimates that 44 respondents (19 cigarette filler and RYO tobacco receiving authorizations and 25 smokeless receiving authorizations) 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 the two smoking regimens. The total expected burden is 17,996 hours for this section.

The total estimated burden for this information collection is 19,193 hours and 424 respondents. Our estimated burden for the information collection reflects an overall increase of 269 respondents 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: February 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02478 Filed 2–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

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 March 9, 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 0910–0322. 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.

Environmental Impact Considerations

OMB Control Number 0910–0322—Extension

I. Background

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information ''Environmental Impact Considerations.'' The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting Agency action require the submission of a claim for categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) (21 CFR 25.15(a) and (d)) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (21 CFR 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) (21 CFR 25.40(a) and (c)) specifies the content requirements for EAs for non-excluded actions.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the Agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. When the Agency finds that no significant environmental effects are expected, the Agency prepares a finding of no significant impact.

In the **Federal Register** of August 25, 2021 (86 FR 47501), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

II. Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Drug Evaluation and Research)

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 (21 CFR 25.30) or § 25.31 (21 CFR 25.31), or an EA under § 25.40. Annually, FDA receives approximately 5,503 INDs from 3,717 sponsors; 142 NDAs from 111 applicants; 3,285 supplements to NDAs from 516 applicants; 35 biologic license applications (BLAs) from 32 applicants; 777 supplements to BLAs from 89 applicants; 743 ANDAs from 239 applicants; and 11,438 supplements to ANDAs from 482 applicants. FDA estimates that it receives approximately 21,923 claims for categorical exclusions as required under § 25.15(a) and (d) and 13 EAs as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA. Based on recent numbers, we now estimate a total of 21,936 annual responses and 219,584 hours for human drugs (an increase of 6,489 responses and 62,088 hours).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	5,186	4.2273	21,923	8	175,384
25.40(a) and (c)	14	0.9285	13	3,400	44,200
Total	219,584				

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

III. Estimated Annual Reporting Burden for Medical Devices

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or 21 CFR 25.34 or an EA under § 25.40. In 2020, FDA received an average of 62 claims (original PMAs and supplements) for categorical exclusions as required under § 25.15(a) and (d), and 0 EAs as required under § 25.40(a) and (c). FDA estimates that approximately 62 respondents will submit an average of 1 application for categorical exclusion annually. Based on information provided by sponsors, FDA estimates that it takes approximately 6 hours to prepare a claim for a categorical exclusion. Based on recent numbers, we now estimate a total of 62 annual responses and 372 hours for medical devices (an increase of 12 responses and 72 hours).

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	62	1	62	6	372

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

IV. Estimated Annual Reporting Burden for Biological Products, Drugs, and Medical Devices in the Center for Biologics Evaluation and Research

Under 21 CFR 601.2(a), BLAs as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of categorical exclusion under § 25.30 or § 25.32 (21 CFR 25.32) or an EA under § 25.40. Annually, FDA receives approximately 11 BLAs from 11 applicants, 1,080 BLA supplements to license applications from 160 applicants, 7,017 INDs from 2,087 sponsors, 1 NDA from 1 applicant, 16 supplements to NDAs from 6 applicants, 1 ANDA from 1 applicant, 3 supplements to ANDAs from 2 applicants, 1 PMA from 1 applicant, and 79 PMA supplements from 19 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it has received approximately 7,150 claims for categorical exclusion as required under § 25.15(a) and (d) annually and 4 EAs as required under § 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 3,575 respondents will submit an average of 2 applications for categorical exclusion and 4 respondents will submit an average of 1 EA. Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim of categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product. Based on recent numbers, we now estimate a total of 7,154 annual responses and 70,800 hours for human drugs (an increase of 6,658 responses and 60,048 hours).

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,575	2	7,150	8	57,200
25.40(a) and (c)	4	1	4	3,400	13,600
Total					70,800

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

V. Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); supplemental NADAs and ANADAs (21 CFR 514.8(a)(1)); investigational new animal drug applications and generic investigational new animal drug applications (21 CFR 511.1(b)(10)); and food additive petitions (21 CFR 571.1(c)) must contain a claim for categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 1,140 claims for categorical exclusion as required under § 25.15(a) and (d) and 9 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 114 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that nine respondents will submit an average of one EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of categorical exclusion and an average of 2,160 hours to prepare an EA. Based on recent numbers, we now estimate a total of 22,860 hours for animal drugs (a decrease of 22,860 hours).

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	114	10	1,140	3	3,420

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	9	1	9	2,160	19,440
Total					22,860

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

VI. Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalences (SEs), exemption from SEs, and modified risk tobacco product applications (MRTPAs) must contain a claim for categorical exclusion or an EA. The majority of the EA burden for tobacco products is covered under already existing information collections. The burden for SEs is currently approved under OMB control number 0910–0673; the burden for PMTAs are currently approved under OMB control number 0910–0768; and the burden for SE exemptions are currently approved under OMB control number 0910–0684.

FDA's estimates are based on actual report data from fiscal year (FY) 2018 to FY 2020. On average, FDA estimated it received approximately 14 MRTPAs from 14 respondents. Based on updated data for this collection, FDA estimates 14 EAs from 14 respondents. A total of 14 respondents will submit an average of 1 application for environmental assessment. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA. Based on recent MRTPA numbers, we now estimate a total of 14 annual responses and 1,120 hours for Tobacco Products (a decrease of 13 responses and 1,040 hours).

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	14	1	14	80	1,120

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

Since the last OMB approval, we have adjusted our burden estimate. We estimate the total burden for this information collection to be 30,315 annual responses, and 314,736 hours. These estimates reflect an overall increase of 13,463 responses and 94,078 hours. We attribute the adjustments to expected fluctuations in the number of responses the various centers in FDA have received over the last few years.

Dated: February 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02475 Filed 2–4–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0053]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of January 11, 2022. In the notice of availability, FDA requested comments on draft guidance for industry and FDA staff entitled ''Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published January 11, 2022 (87 FR 1417). Submit either electronic or written comments on the draft guidance by April 11, 2022, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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