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) 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: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 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) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 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) 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 June 7, 2018 (83 FR 26477), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) One commenter requested that FDA should categorically exclude all categories of SE applications from the EA requirement.

(Response) FDA appreciates this comment. We note, however, that any action to establish a categorial exclusion would need to be undertaken through a notice and comment rulemaking procedure.

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 or § 25.31, or an EA under § 25.40. Annually, FDA receives approximately 3,687 INDs from 2,456 sponsors; 140 NDAs from 116 applicants; 3,192 supplements to NDAs from 443 applicants; 28 biologic license applications (BLAs) from 22 applicants; 464 supplements to BLAs from 52 applicants; 1,152 ANDAs from 248 applicants; and 6,774 supplements to ANDAs from 384 applicants. FDA estimates that it receives approximately 15,437 claims for categorical exclusions as required under § 25.15(a) and (d) and 10 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.

Table 1.--Estimated Annual Reporting Burden for Human Drugs[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and(d)	3,724	4.1453	15,437	8	123,496
25.40(a) and (c)	10	1	10	3,400	34,000
Total					157,496

[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 § 25.34 or an EA under § 25.40. In 2017, FDA received an average of 50 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 50 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.

Table 2.--Estimated Annual Reporting Burden for Medical Devices[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and (d)	50	1	50	6	300

[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 or an EA under § 25.40. Annually, FDA receives approximately 34 BLAs from 18 applicants, 801 BLA supplements to license applications from 156 applicants, 345 INDs from 256 sponsors, 1 NDA from 1 applicant, 26 supplements to NDAs from 8 applicants, 1 ANDA from 1 applicant, 1 supplement to ANDAs from 1 applicant, 8 PMAs from 3 applicants,

and 33 PMA supplements from 16 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA has received approximately 481 claims for categorical exclusion as required under § 25.15(a) and (d) annually and 2 EAs as required under § 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 247 respondents will submit an average of 2 applications for categorical exclusion and 2 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.

Table 3.--Estimated Annual Reporting Burden for Biological Products[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and (d)	247	2	494	8	3,952
25.40(a) and(c)	2	1	2	3,400	6,800
Total					10,752

[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); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs) and generic investigational new animal drug applications (JINADs), and 21 CFR 571.1(c) food additive petitions 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 810 claims for categorical exclusion as required under § 25.15(a) and (d) and 22 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 81 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that 22 respondents will submit an average of 1 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.

Table 4.--Estimated Annual Reporting Burden for Animal Drugs [1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and (d)	81	10	810	3	2,430
25.40(a) and (c)	22	1	22	2,160	47,520
Total					49,950

[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 (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. After further review, the agency has concluded that the majority of the EA burden for tobacco products is covered under already existing information collections. To avoid double counting, the agency has removed the burden which is approved under other FDA information collections. The burden for SEs are currently approved under OMB control number 0910-0673; the burden for PMTAs are currently approved under OMB control number 0910-0768; 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) 2015 to FY 2017, on average FDA estimated it received approximately 27 modified risk tobacco product applications (MRTPAs) from 27 respondents. Based on updated data for this collection, FDA estimates 27 EAs from 27 respondents. A total of 27 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.

Table 5.--Estimated Annual Reporting Burden for Tobacco Products [1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.40(a) and (c)	27	1	27	80	2,160

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

The Estimated Annual Reporting Burden for Human Foods is no longer a part of this information collection. The burden has now been incorporated into OMB control number 0910-0541.

Our estimated burden for the information collection reflects an overall decrease of 10,566 hours (currently approved 231,224) and a corresponding decrease of 11,364 annual responses (currently approved 15,527). The new estimated totals are 220,658 hours and 4,163 annual responses. We attribute this adjustment to the removal of the majority tobacco burden from this collection, and the number of EA submissions we received since the last extension.

Dated: November 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-26556 Filed: 12/6/2018 8:45 am; Publication Date: 12/7/2018]