



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0961]

Agency Information Collection Activities; Proposed Collection; 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 (the PRA).

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 oir_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@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--21 CFR Part 25

OMB Control Number 0910-0322--Extension

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 September 8, 2015 (80 FR 53807), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Under §§ 312.23(a)(7)(iv)(c), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(c), 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 3,677 INDs from 2,501 sponsors; 120 NDAs from 87 applicants; 2,718 supplements to NDAs from 399 applicants; 9 biologic license applications (BLAs) from 8 applicants; 317 supplements to BLAs from 43 applicants; 1,475 ANDAs from 300 applicants; and 5,448 supplements to ANDAs from 318 applicants. FDA estimates that it receives approximately 13,663 claims for categorical exclusions as required under § 25.15(a) and (d), and 11 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 Drugs¹

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)	3,416	4	13,664	8	109,312
25.40(a) and (c)	11	1	11	3,400	37,400
Total					146,712

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

Estimated Annual Reporting Burden for Human Foods

Under 21 CFR 71.1, 171.1, 170.39, and 170.100, food additive petitions, color additive petitions, requests from exemption from regulation as a food additive, and submission of a food contact notification for a food contact substance must contain either a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA receives approximately 97 industry submissions. FDA received an annual average of 42 claims of categorical exclusions as required under § 25.15(a) and (d) and 33 EAs as required under § 25.40(a) and (c). FDA estimates that approximately 42 respondents will submit an average of 1 application for categorical exclusion and 33 respondents will submit an average of 1 EA. FDA

estimates that, on average, it takes petitioners, notifiers, or requestors approximately 8 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

Table 2.--Estimated Annual Reporting Burden for Human Foods¹

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)	42	1	42	8	336
25.40(a) and (c)	33	1	33	210	6,930
Total					7,266

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

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 2012 to 2014, FDA received an average of 39 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 39 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 3.--Estimated Annual Reporting Burden for Medical Devices¹

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)	39	1	39	6	234

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

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 4.--Estimated Annual Reporting Burden for Biological Products¹

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.

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 21 CFR 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.33 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 698 claims for categorical exclusion as required under § 25.15(a) and (d), and 10 EAs as required under § 25.40(a) and (c). FDA estimates that approximately 70

respondents will submit an average of 10 applications for categorical exclusion and 10 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 5.--Estimated Annual Reporting Burden for Animal Drugs¹

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)	70	10	700	3	2,100
25.40(a) and (c)	10	1	10	2,160	21,600
Total					23,700

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

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. In 2015, FDA estimated it will receive approximately 5 premarket review of new tobacco PMTAs from 5 respondents, 509 reports intended to demonstrate the substantial equivalence of a new tobacco product (SEs) from 509 respondents, 15 exemption from substantial equivalence requirements applications (SE Exemptions) from 15 respondents, and 3 modified risk tobacco product applications (MRTPAs) from 3 respondents. FDA is not accepting claims for categorical exclusions at this time, and estimates that there will be 532 EAs from 532 respondents as required under §§ 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 532 respondents will submit an average of 1 application for environmental assessment. Part of the information in the EA will be developed while writing other parts of a PMTA, SE, Exemption from SE, or MRTPA. 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 6.--Estimated Annual Reporting Burden for Tobacco Products¹

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)	532	1	532	80	42,560

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

Dated: March 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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