4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0706]

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: Submit written comments (including recommendations) 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 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

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information "Environmental Impact Considerations." The National Environmental Policy Act of 1969 (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 106(b) of NEPA provides for the preparation of an environmental impact statement (EIS) for a proposed Federal Agency action requiring an environmental document that has a reasonably foreseeable significant effect on the quality of the human environment. Section 106(b) of NEPA further provides for the preparation of an environmental assessment (EA) for a proposed Federal Agency action that does not have a reasonably foreseeable significant effect on the quality of the human environment, or if the significance of such effect is unknown, unless the Agency finds that the proposed Federal Agency action is excluded pursuant to one of the Federal Agency's categorical exclusions (CE). Certain classes of actions that a Federal Agency has determined normally do not, individually or cumulatively, have a significant effect on the quality of the human environment are ordinarily--or categorically--excluded from the requirement to prepare an EA or EIS (see, e.g., section 106(a) of NEPA).

This information collection supports implementation of NEPA, consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service (PHS) Act. Certain requests for FDA action require the preparation of a CE, EA, or EIS. FDA's regulations in part 25 (21 CFR part 25) implement the portions of NEPA that are relevant to FDA in a manner that is consistent with FDA's authority under the FD&C Act and the PHS Act. These regulations (Environmental Impact Considerations) set forth FDA procedures with regard to NEPA requirements by identifying actions that require the preparation of an environmental document and discussing the preparation of such documents. These regulations also supplement the procedures included in the "HHS General Administration Manual, part 30: Environmental Protection" (45 FR 76519, November 19, 1980).

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 that may result in the need for an EA. 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) specify the content requirements for EAs for non-excluded actions. Where the Agency finds that no significant environmental effects is expected, a finding of no significant impact is prepared.

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 submitted information is used to prepare and circulate to the public an EIS, when applicable, 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, when applicable, 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. In cases requiring an EIS, the Agency prepares a record of decision pursuant to § 25.43.

In the *Federal Register* of July 2, 2025 (90 FR 29011), 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:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Part 25; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sections 25.20, 25.40, and 25.42; Actions Requiring an EA or an EIS:					
Center for Drug Evaluation and Research (CDER)	13	1	13	3,400	44,200
Center for Devices and Radiological Health (CDRH)	66	1	66	3,400	224,400
Center for Biologics Evaluation and Research (CBER)	4	1	4	3,400	13,600
Center for Veterinary Medicine (CVM)	11	1	11	2,160	23,760
Center for Tobacco Products (CTP)	14	1	14	80	1,120
Human Foods Program (HFP)	60	1	60	180	10,800
Subtotal	168		168		317,880
Section 25.15(a) and (d); actions subject to CE:					
CDER	3,999	5.0765	20,301	8	162,408
CDRH	66	1	66	6	396
CBER	2,383	3	7,149	8	57,192
CVM	116	6.47	751	3	2,253
HFP	50	1	50	8	400
Subtotal	6,614		28,317		222,649
Total	6,782		28,485		540,529

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

CDER:

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 CE under § 25.30 or § 25.31, or an EA under § 25.40.

CDRH:

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approval applications (PMAs) (original PMAs and supplements) must contain a claim for CE under § 25.30 or § 25.34 or an EA under § 25.40.

CBER:

Under 21 CFR 601.2(a), biologic license applications (BLAs) as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of CE under § 25.30 or § 25.31 or an EA under § 25.40.

CVM:

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 and generic investigational new animal drug applications, and 21 CFR 571.1(c) food additive petitions (FAPs), 21 CFR 516.129(c)(9) requests for determination of eligibility for indexing, and 21 CFR 510.205(e)(7) establishment of an import tolerance must contain a claim for CE under § 25.30, § 25.32, or § 25.33, or an EA under § 25.40.

CTP:

Under sections 905, 910, and 911 of the FD&C 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 must contain a claim for a CE or an EA. Upon evaluation, we have concluded that the majority of the EA burden for tobacco products is accounted for in other information collections currently

approved by OMB. The burden we attribute to SEs is currently approved in OMB control number 0910-0673; the burden we attribute to PMTAs is currently approved in OMB control number 0910-0768; and the burden we attribute to SE exemptions is currently approved in OMB control number 0910-0684.

HFP:

Under § 25.20, the following actions normally require at least the preparation of an EA, unless the action qualifies for categorical exclusion: establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in § 25.30(k) or § 25.31(a), (b), (c), (h), (i), or (j), or §25.32(a) or (p); withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in § 25.31(d) or (k), § 25.32(m), or § 25.33(g) or (h); approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under 21 CFR 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this claim of CE at one respondent making one submission a year for a total of one annual submission. The burden for submitting a claim of CE is captured under § 25.15(a) and (d).

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. Our estimated burden for the information collection reflects an overall increase of 215,125 hours and a decrease of 1,938 responses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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