

ENVIRONMENTAL IMPACT CONSIDERATIONS

21 CFR Part 25

OMB Control No. 0910-0322 – Revision

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations that implement section 102(2) of the National Environmental Policy Act of 1969 (NEPA). Regulations in part 25 (21 CFR part 25), *Environmental Impact Considerations*, set forth FDA procedures with regard to NEPA requirements (part 25, subpart A); identify actions that require the preparation of an Environmental Assessment (EA) (part 25, subpart B); explain categorical exclusions (CEs) (part 25, subpart C); and discuss the preparation of documents (part 25, subpart D). The regulations also supplement procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in [40 CFR parts 1500](#) through [1508](#) and the procedures included in the “*HHS General Administration Manual, part 30: Environmental Protection*” ([45 FR 76519](#) to 76534, November 19, 1980). 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. Accordingly, implementing regulations in 21 CFR part 25 require the submission of a claim for a CE or an EA for all applications or petitions requesting agency action.

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. Sections 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 (FONSI) is prepared. We are revising the information collection to include burden that may result from recommendations found in the guidance document, “*Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition*” (May 2006), that do not themselves create requirements, but rather, explain FDA procedures. This information collection activity is currently approved in OMB Control No. 0910-0541.

We therefore request OMB approval for the information collection provisions found in 21 CFR part 25, as well as information collection associated with recommendations found in the referenced agency guidance document pertaining to submissions to CFSAN.

2. Purpose and Use of the Information Collection

FDA uses the information collection to assess the environmental impact of its actions. NEPA directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements.

3. Use of Improved Information Technology and Burden Reduction

We estimate 95% of respondents will use electronic means to fulfill the information collection. Submissions made to CFSAN are supported by the CFSAN Online Submission Module (COSM). COSM is part of FDA's Electronic Submission Gateway (ESG), an electronic system that also supports a number of other information collections. We also accept information supporting claims of categorical exclusion or an EA by e-mail.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Upon OMB review and approval of this request, we intend to discontinue control no. 0910-0541.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. There are no legal obstacles to reduce the burden for this collection of information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information. Information collection recommended in the guidance does not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, or the use of statistical methods. However, a firm's submission of a claim of categorical exclusion or an EA may contain trade secret and commercial confidential information. This information is protected by FDA as set out below in the response to item 10 of this supporting statement.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60 day notice soliciting public comment in the Federal Register of August 25, 2021(86 FR 47501). Although one comment was received, it was not responsive to the four collection of information topics solicited.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents to the information collection. The information is necessary to obtain a benefit (action by FDA).

10. Assurance of Confidentiality Provided to Respondents

Information submitted to FDA in a claim of categorical exclusion or an EA may contain trade secret and commercial confidential information. Only information that is releasable under the agency’s regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the Federal Food, Drug, and Cosmetic Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

In preparing this supporting statement, we also consulted with our Privacy Office to ensure appropriate handling of information collected. Although personally identifiable information (PII), or other data of a personal nature, is collected in conjunction with the regulations in 21 CFR part 25, the information is provided as part of requests for agency action governed by product specific submissions. We have determined, therefore, that although PII is collected in conjunction with associated submissions to the agency, the particular notice and other requirements of the Privacy Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in the environmental impact requirements.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hourly Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

21 CFR part 25; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Section 25.40(c); actions excluded from the requirement to prepare EA or EIS:					

21 CFR part 25; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Center for Drug Evaluation and Research (CDER)	14	0.9285	13	3,400	44,200
Center for Devices and Radiological Health (CDRH)	0	-	0	-	0
Center for Biologics Evaluation and Research (CBER)	4	1	4	3,400	13,600
Center for Veterinary Medicine (CVM)	9	1	9	2,160	19,440
Center for Tobacco Products (CTP)	14	1	14	80	1,120
Center for Food Safety and Applied Nutrition (CFSAN)	57	1	57	180	10,260
Subtotal			97		88,620
Section 25.15(d); actions subject to CE:					
CDER	5,186	4.2273	21,923	8	175,384
CDRH	62	1	62	6	372
CBER	3,575	2	7,150	8	57,200
CVM	114	10	1,140	2,160	3,420
CTP	0	-	0	-	0
CFSAN	51	1	51	8	408
Subtotal			30,326		236,784
Total			30,423		325,404

¹ There are no capital, or operational and maintenance costs associated with the information collection.

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 approvals (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 § 25.32 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 must contain a claim for CE under § 25.30 or § 25.32 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.

CFSAN:

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed in § 25.32 that FDA 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).

12b. Annualized Cost Burden Estimate

Assuming a wage rate of \$84/hour for preparing and submitting the information in accordance with 21 CFR part 25 and multiplying that figure by the total number of annual burden hours (325,404), we calculate an annual cost to industry of \$27,333,936.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

WE allocate an estimated 8 full-time employees (FTEs) for the review of submissions associated with 21 CFR part 25. Assuming an annual salary of \$180,000 per FTE, we calculate an estimated cost to the Federal government of \$1,440,000.

15. Explanation for Program Changes or Adjustments

As a result of revising the information collection to include submissions made to CFSAN, there is an increase of burden by 108 responses and 10,668 hours annually. However, upon review of the ICR we noted an inadvertent calculation error in our previous submission with regard to the annual number of responses; we have corrected the error with this submission and thus the ICR reflects an adjustment of -8,829.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish tabulated results of the information collection requirements that are imposed by 21 CFR part 25.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB control number as required by 5 CFR 1320.5 (and 5 CFR 1320.8(b) (1)). Because documents are more frequently being accessed electronically, however, we have implemented technological changes enabling us to display the expiration date by linking to approval information found at www.reginfo.gov. We now include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval. We are taking this approach to improve compatibility with our current our website platform (Drupal).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.