ENVIRONMENTAL IMPACT CONSIDERATIONS

21 CFR Part 25

OMB Control No. 0910-0322 – Extension

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 in part 25 (21 CFR part 25) that implement section 102(2) of the National Environmental Policy Act of 1969 (NEPA), consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service (PHS) Act.

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).

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. To assist industry, we published 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), which does not create requirements, but rather, explains FDA procedures.

We therefore request OMB approval for the information collection provisions found in 21 CFR part 25, information collections discussed in this supporting statement and associated with recommendations found in the referenced agency guidance documents.

2. Purpose and Use of the Information Collection

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.

Description of Respondents: Respondents to this collection of information include manufacturers, processors, and importers who must provide an environmental impact assessment or are requesting a categorical exclusion for FDA-regulated products.

3. Use of Improved Information Technology and Burden Reduction

We estimate 95% of respondents will use electronic means to fulfill the information collection. 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.

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. However, a firm's submission of a claim of CE 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 July 02, 2025 (90 FR 29011). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

    Information submitted to FDA in a claim of CE 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)).

    Privacy Act

    In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and 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.

Freedom of Information Act

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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 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 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 (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, § 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 0910-0879; 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 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 (540,529), we calculate an annual cost to industry of $45,404,436.

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 $185,000 per FTE, we calculate an estimated cost to the Federal government of $1,480,000.

15. Explanation for Program Changes or Adjustments

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.

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 website platform (Drupal).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.