UNITED STATES FOOD & DRUG ADMINISTRATION

Environmental Impact Considerations
21 CFR Part 25

OMB Control No. 0910-0322

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. 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. The FDA NEPA regulations are contained in 21 CFR part 25. All applications or petitions requesting agency action require the submission of a claim for a 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. Sections 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. 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 of 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 (FONSI).

We therefore request OMB approval for the information collection associated with reporting of environmental impact considerations, as discussed in this supporting statement.

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 determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects 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 notices also filed for comment at the Environmental Protection Agency (EPA). If the Agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact (FONSI).

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that approximately 95% of the respondents to this collection of information will use electronic means to fulfill the Agency's requirements or request for information.

4. Efforts to Identify Duplication and Use of Similar Information

FDA avoids duplication by encouraging applicants to reference in their environmental documents data and information presented in other documents that are available to FDA and the public (21 CFR 25.40(d)). FDA intends to focus environmental reviews on the use and disposal from use of FDA regulated articles. Because FDA actively works to ensure the consistency of its protocols with those prescribed by EPA, the American Society for Testing and Materials (ASTM), and Organization for Economic Co-operation and Development (OECD), FDA avoids unnecessary duplication of environmental testing. Thus, environmental testing that has already been performed will not have to be repeated by a different protocol when applicants move from one regulatory Agency to another and from one country to another for approvals of the same chemical substance.

Where possible, existing data are used by FDA in evaluating the environmental impact of an industry-sponsored application or petition. To the extent publicly available, data in FDA files may be cross-referenced, data available in the scientific literature may be submitted, and data gathered for other government Agencies, such as EPA, may be used in support of the environmental review of an application to FDA.

FDA recognizes that there are instances where the same substance may be the subject of separate environmental analyses by another Agency, for example by EPA. FDA has determined that separate environmental review is not necessary for FDA approval of a food additive petition or FDA granting a request for an exemption from regulations as a food additive if the substance is already registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the same use requested in the petition. Although both agencies have worked to eliminate duplication of effort, applications submitted to FDA sometimes involve a different use of a chemical substance than the use(s) reviewed by EPA and the patterns of environmental introduction often vary. Therefore, in some circumstances, a document prepared by FDA or another Agency may not suffice as the NEPA document.

5. Impact on Small Businesses or Other Small Entities

For both large and small entities, FDA has identified the types of information necessary to review the environmental impact of a new product and, where possible, provides case-by case guidance on the specific types of information required for a particular action. FDA does not have the resources to perform a firm's environmental studies and the information gathering necessary for the evaluation of a new product. However, small manufacturers may request help in applying for approval from the FDA office that works with small manufacturers. Because FDA has identified categories of actions that are categorically excluded from the requirement to prepare an EA and EIS, fewer EA's and EIS's are likely to be required from small businesses.

6. Consequences of Collecting the Information Less Frequently

Industry-sponsored applications and petitions are submitted on an occasional basis to obtain permission to market a new product or to expand the usage of a currently regulated product. If the frequency of collection for environmental impact data were reduced, the agency could not assess the environmental impact of approving applications. Failure to take environmental factors into account in the Agency decision making would leave the Agency susceptible to court challenge and may result in unnecessary delays in the approval for marketing of products. 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

Data collection for applications is consistent with these guidelines. There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for 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

FDA has not provided and has no intention to provide any payment or gift to respondents under the revisions of part 25.

10. Assurance of Confidentiality Provided to Respondents

NEPA requires that EA's and EIS's be made available for public review. However, 21 CFR 25.50(b) recognizes that FDA actions involving investigations, review, and approval of applications and premarket notifications for human drugs, animal drugs, biologic products, devices, and tobacco products are protected from disclosure under the Trade Secret Act (TSA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and 21 CFR part 20. Additionally, under 21 CFR 25.51 (a), data constituting trade secrets or confidential information under the TSA or the FFDCA must not be included in the portion of environmental documents that is made public. Thus, environmental information will be made available to the public to the extent permitted.

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

12 a. Annualized Hour Burden Estimate

Estimated Annual Reporting Burden for Human Drugs (Including Biologics in 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 categorical exclusion under § 25.30 or § 25.31, or an EA under § 25.40. Annually, FDA receives approximately 5,503 INDs from 3,717 sponsors; 142 NDAs from 111 applicants;

3,285 supplements to NDAs from 516 applicants; 35 biologic license applications (BLAs) from 32 applicants; 777 supplements to BLAs from 89 applicants; 743 ANDAs from 239 applicants; and 11,438 supplements to ANDAs from 482 applicants. FDA estimates that it receives approximately 21,923 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

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)	5,186	4.2273	21,923	8	175,384
25.40(a) and (c)	14	0.9285	13	3,400	44,200
Total					219,584

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. FDA has received approximately 62 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 62 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

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)	62	1	62	6	372

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 11 BLAs from 11 applicants, 1,080 BLA supplements to license applications from 160 applicants, 7,017 INDs from 2,087 sponsors, 1 NDA from 1 applicant, 16 supplements to NDAs from 6 applicants, 1 ANDA from 1 applicant, 3 supplements to ANDAs from 2 applicants, 1 PMA from 1 applicant, and 79 PMA supplements from 19 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 7,150 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 3,575 respondents will submit an average of 2 applications for categorical exclusion and 4 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

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)	3,575	2	7,150	8	57,200
25.40(a) and(c)	4	1	4	3,400	13,600
Total					70,800

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 received approximately 1,140 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 114 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that 9 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

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)	114	10	1,140	3	3,420
25.40(a) and (c)	9	1	9	2,160	19,440
Total					22,860

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), substantial equivalences (SEs), Exemption from SEs, and modified risk tobacco product applications (MRTPAs) 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) 2018 to FY 2020, on average FDA estimated it received approximately 14 MRTPSAs from 14 respondents. Based on updated data for this collection, FDA estimates 14 EAs from 14 respondents. A total of 14 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

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)	14	1	14	80	1,120

Table 6.--Estimated Annual Total Reporting Burden for All Centers

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15 (a) & (d)	8,937	-	39,212	-	236,376
25.40 (a) & (c)	41	-	40	-	78,360
Total	8,978	-	39,252	-	0

12b. Annualized Cost Burden Estimate

FDA's Economics Staff estimates the average industry wage rate of $84.00 per hour for preparing and submitting the information collection requirements associated with marketing applications. Based on a total industry burden of 314,736 hours, the annualized cost burden to respondents would be $26,437,824.

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Businesses	314,736	$84.00	$26,437,824

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

FDA estimates that a total of approximately 8 FTEs are devoted to the review of submissions associated with 21 CFR part 25. Based on an estimate of $180,000 per FTE, the annualized cost burden to FDA would be approximately $1,440,000.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 94,078 hours (currently approved 220,658) and a corresponding increase of 22,400 annual responses (currently approved 16,852). The new estimated totals are 314,736 hours and 39,252 annual responses (as shown in table 6). We attribute this adjustment to the number of EA submissions, and categorical exclusions we received since the last extension, and the adjustment of burden for the agencies centers.

A summary of changes to burden is as follows:

In reporting burden for Human Drugs, table 1, the net increase in burden is 62,088 hours. The number of respondents submitting categorical exclusions is expected to increase by 1,462, and the responses per respondent has increase slightly, resulting in an increase of 51,888 burden hours. In addition, the number of EAs is expected to increase by 4, and the responses per respondent has decreased slightly, resulting in an increase of 10,200 burden hours.

In reporting burden for Medical Devices, table 2, the net increase in burden is 72 hours. The number of respondents submitting categorical exclusions is expected to increase by 12, resulting in an increase of 72 burden hours.

In reporting burden for Biological Products, table 3, the net increase is 60,048 burden hours. The number of respondents submitting categorical exclusions is expected to increase by 3,328, resulting in an increase of 53,248 burden hours. In addition, the number of EAs is expected to increase by 2, resulting in an increase of 6,800 burden hours.

In reporting burden for Animal Drugs, table 4, the net decrease in burden is 27,090. The number of respondents submitting categorical exclusions has increased by 33, resulting in an increase of 990 burden hours. The numbers of EAs have decreased by 13 respondent, resulting in a decrease of 28,080 burden hours.

In reporting for Tobacco Products, table 5, the net decrease in burden is 1,040. The number of respondents submitting environmental assessments is expected to decrease by 13, resulting in a burden hour decrease of 1,040 burden hours.

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

There are no forms associated with this collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.