Environmental Impact Considerations
21 CFR Part 25
0910-0322
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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.

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 nonexcluded 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).

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 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).

The respondents to this collection are primarily from the private sector businesses.

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.

For human drugs, the submissions under 21 CFR part 25 are part of an application for marketing. Some of the steps that FDA has taken to facilitate the electronic submission of marketing applications include issuing a final rule on December 11, 2003 to govern the format in which certain labeling is required to be submitted for review with NDAs, certain BLAs, ANDAs, supplements, and annual reports. The final rule required the electronic submission of the content of labeling (i.e., the content of the package insert or professional labeling, including all text, tables, and figures) in NDAs, certain BLAs, ANDAs, supplements, and annual reports electronically in a form that FDA can process, review, and archive.

FDA has also developed guidances for industryto improve the use of information technology in the submission of marketing applications for human drugs and related reports.

These guidance documents are available at FDA's web site http://www.fda.gov/cder/guidance/index.htm.

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 September 28, 2012 (77 FR 59619).
Two PRA-related comments were received from one commenter..

(Comment) The commenter indicated that FDA underestimates the hours required to complete an environmental assessment for tobacco products, and that FDA's 12 hours burden estimate per response is substantially underestimated. The commenter said, based on their experience, that it should take approximately 80 hours to complete an environmental assessment for tobacco products.

(Response) FDA agrees with this comment. Upon further review of the number of hours required to complete an environmental assessment for tobacco products, FDA has determined that 12 hours is too low of an estimate, and has revised the burden estimate per response for completing an environmental assessment for tobacco products from 12 to 80 hours. Part of the information in an EA will be developed while writing other parts of a PMTA, SE, Exemption from SE, or modified risk tobacco product application. The burden was revised based on FDA's experience, previous information provided by potential sponsors, and information provided by this commenter. FDA now estimates that it takes approximately 80 hours to prepare an EA.kes approximately 80 hours to prepare an EA.

(Comment) The commenter also encouraged the Agency to establish categorical exclusions for environmental assessments for tobacco product submittals under Section 905(j) of the Federal Food, Drug, and Cosmetic Act.

(Response) FDA has decided to not establish categorical exclusions for tobacco products at this time.

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 21 CFR 312.23(a)(7)(iv)(3), 21 CFR 314.50(d)(1)(iii), and 21 CFR 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. In 2011, FDA received 2,818 INDs from 2,064 sponsors, 99 NDAs from 79 applicants, 3,247 supplements to NDAs from 376 applicants, 5 biologic license applications (BLAs) from 5 applicants, 287 supplements to BLAs from 50 applicants, 895 ANDAs from 195 applicants, and 5,348 supplements to ANDAs from 299 applicants. FDA estimates that it receives approximately 12,699 claims for categorical exclusions as required under §§ 25.15(a) and (d), and 20 EAs as required under §§ 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 3,175 respondents will submit an average of 4 applications for categorical exclusion and 10 respondents will submit an average of 1 environmental assessment. 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[1]

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15 (a) & (d)	3,175	4	12,700	8	101,600
25.40 (a) & (c)	10	1	10	3,400	34,000
Total					135,600

[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 (FCN) 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**.** In 2011, FDA received 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) (the remainder of which were withdrawn). Therefore, over the

next 3 years, 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 environmental assessment. FDA estimates that, on average, it takes petitioners, notifiers, or requestors approximately 3 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

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

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15 (a) & (d)	42	1	42	8	336
25.40 (a) & (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 21 CFR 814.20(b)(11), pre-market approvals (original PMAs and supplements) must contain a claim for categorical exclusion under §§ 25.30 or 25.34 or an EA under § 25.40. In 2011, FDA received approximately 52 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). Therefore, over the next 3 years, FDA estimates that approximately 52 respondents will submit an average of 1 application for categorical exclusion. Based on information provided by less than 10 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 Devices[1]

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15 (a) & (d)	52	1	52	6	312
Total					312

[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 CBER

Under 21 CFR 601.2(a), BLAs as well as INDs (21 CFR 312.23), NDAs (21 CFR 314.50), ANDAs (21 CFR 314.94), and PMAs (21 CFR 814.20), must contain either a claim of categorical exclusion under §§ 25.30 or 25.32 or an EA under § 25.40. In 2011, FDA received 14 BLAs from 14 applicants, 831 BLA supplements to license applications from 153 applicants, 288 INDs from 210 sponsors, 1 NDA from 1 applicant, 37 supplements to NDAs from 9 applicants, 1 ANDA from 1 applicant, 12 supplements to ANDAs from 2 applicants, and 45 PMA supplements from 11 applicants**.** FDA estimates

that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it received approximately 481 claims for categorical exclusion as required under §§ 25.15(a) and (d), and 2 EAs as required under §§ 25.40(a) and (c). Therefore, over the next 3 years, 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 environmental assessment. 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 Products

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15 (a) & (d)	247	2	494	8	3,952
25.40 (a) & (c)	2	1	2	3,400	6,800
Total[2]					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), § 514.8(a)(1) supplemental NADAs and ANADAs, § 511.1(b)(10) investigational new animal drug applications (INADs), and § 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**.** In 2011, FDA's Center for Veterinary Medicine (CVM) 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). Therefore, over the next 3 years, 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 environmental assessment. 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 Drugs

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15 (a) & (d)	70	10	700	3	2,100
25.40 (a) & (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, Drugs, and Cosmetic Act (FD&C Act), PMTAs, SEs, Exemption from SEs, and Modified Risk tobacco products must contain a claim for categorical exclusion or an EA**.** In 2011, FDA estimated it will receive approximately 20 premarket review of new tobacco product applications and supplements (PMTAs) from 20 respondents, 150 reports intended to demonstrate the substantial equivalence of a new tobacco product (SEs) from 150 respondents, 500 exemption from substantial equivalence requirements applications (SE Exemptions) from 500 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 135 EAs from 135 respondents as required under 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that approximately 135 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 modified risk tobacco product application. Based on FDA's experience, previous information provided by potential sponsors, information provided by a commenter to this collection of information, 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.kes approximately 80 hours to prepare an EA.

Table 6.--Estimated Annual Reporting Burden for Tobacco Products[1]

CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.40 (a) & (c)	135	1	135	80	10,800

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

Table 7.--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)	3,581		13,998		108,300
25.40 (a) & (c)	190		190		80,130
Total[2]					188,430

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

12b. Annualized Cost Burden Estimate

FDA's Economics Staff estimates the average industry wage rate of $74.00 per hour for preparing and submitting the information collection requirements associated with marketing applications. Based on a total industry burden of 203,668 hours, the annualized cost burden to respondents would be $15,071,432.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Businesses	188,430	$74.00	$13,943,820
Total			$13,943,820

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

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

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 $145,000 per FTE, the annualized cost burden to FDA would be approximately $1,160,000.

15. Explanation for Program Changes or Adjustments

    The revised projected burden is expected to decrease by 5,387 hours (193,817 currently approved burden hours minus 188,430 projected burden hours.) The revised estimates are the result of updated data from each of FDA's Centers, and are based on the updated Center information summarized below for claims for categorical exclusions and EAs submitted during 2011 and on the addition of burden for environmental assessments for tobacco products added to this collection.

    A summary of changes to burden is as follows:

    In reporting burden for Human Drugs, table 1, the net decrease in burden is 17,912 hours. The number of respondents submitting categorical exclusions is expected to increase by 4 and the responses per respondent is expected to increase by 0.63, resulting in an increase of 16,088 burden hours. However, the number of environmental assessments is expected to decrease by 10 and burden hours are expected to decrease by 34,000 hours.

    In reporting burden for Human Foods, table 2, the net decrease in burden is 2,385 hours. The number of respondents submitting categorical exclusions is expected to increase by 2 and the responses per respondent are expected to decrease by 0.7, resulting in an increase of 135 burden hours. The numbers of environmental assessments are expected to increase by 9, and the number of responses per respondent is expected to decrease by 0.9, resulting in a burden hour decrease of 2,520 hours.

    In reporting burden for Medical Devices, table 3, the net decrease in burden is 78 hours. The number of respondents submitting categorical exclusions is expected to increase by 11, resulting in an increase of 78 burden hours.

    In reporting burden for Biological Products, table 4, the net decrease in burden is 992 hours. The number of respondents submitting categorical exclusions is expected to increase by 37 and the responses per respondent are expected to increase by 0.29,

resulting in an increase of 992 burden hours. The number of environmental assessments remained the same as currently approved by OMB.

In reporting burden for Animal Drugs, table 5, the net increase in burden is 3,040 hours. The number of respondents submitting categorical exclusions is expected to increase by5, the responses per respondent are expected to decrease by 0.4, and the average burden per response is expected to decrease by 2, resulting in a decrease of 1,280 burden hours. However, the number of environmental assessments is expected to increase by 4, the number of responses per respondent is expected to decrease by 0.3, and the total annual responses are expected to increase by 2, resulting in an increase of 4,320 hours.

In reporting for Tobacco Products, table 6, the net increase in burden is 10,800 hours. The number of respondents submitting environmental assessments was newly added to this collection and therefore is expected to increase by 135, the responses per respondent are expected to be 1, and the average burden per response is expected to be 80 hours, resulting in a burden hour increase of 10,800 hours.

The total burden decrease for this collection, therefore, is 5,387 hours (-17,912 -2,385 + 78 +992 +3,040 + 10,800 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.