

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations—21 CFR Part 25 (OMB Control Number 0910-0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation entitled "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 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.

FDA's NEPA regulations are at part 25 (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. Section 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 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** 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

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.

Estimated Annual Reporting Burden for Human Drugs

Under 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. In 2002, FDA received 2,374 INDs from 1,809 sponsors, 109 NDAs from 79 applicants, 2,575 supplements to NDAs from 276 applicants, 392 ANDAs from 107 applicants, and 3,343 supplements to ANDAs from 222 applicants. FDA estimates that it receives approximately 8,771 claims for categorical exclusions as required under § 25.15(a) and (d) and 22 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 DRUGS¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,031	4.32	8,771	8	70,168
25.40(a) and (c)	22	1	22	3,400	74,800
Total					144,968

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 171.1, 71.1, 170.39, and 170.100, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, and submission of a premarket

notification for a food contact substance must contain a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. In 2002, FDA received 12 food additive petitions and 106 food contact substance notifications. FDA estimates that it received approximately 87 claims of

categorical exclusions as required under § 25.15(a) and (d) and 31 EAs as required under § 25.40(a) and (c). FDA estimates that it takes petitioners or requestors approximately 8 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	56	1.6	87	4	348
25.40(a) and (c)	18	1.7	31	210	6,510