TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(4)	2301	190	6.45	1,226	16	19,616
514.80(b)(5)(i)	2301	190	0.13	25	2	50
514.80(b)(5)(ii)	2301	190	4.06	772	2	1544
514.80(b)(5)(iii)	2301	530	0.11	56	2	112
Total Hours						40,957

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
514.80(e)[2]	530	36.58	19,385	0.5	9,693
514.80(e)[3]	530	4.49	2,379	14	33,320
Total					43,013

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Recordkeeping estimates for § 514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Form FDA 1932.
[3]Recordkeeping estimates for § 514.80(b)(2)(iii), (b)(4), (b)(5), and (c); Form FDA 2301.

The reporting and recordkeeping burden estimates for this collection of information are based on the submission of reports to the Division of Surveillance, CVM. The total annual response numbers are also based on the submission of reports to the Division of Surveillance, CVM. The annual frequency of response was calculated as the total annual responses divided by the number of respondents.

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8023 Filed 9–21–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0105]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 23, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Environmental Impact Considerations—(OMB Control Number 0910–0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation ''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 in 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 (EPA). 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).

In the **Federal Register** of March 29, 2006 (71 FR 15753), FDA published a 60-day notice requesting public comment on the information collection provisions to which FDA received one comment. The comment said it supports the current FDA approach to assessing potential environmental impact under NEPA. However, the comment questioned whether one aspect of the collection of information is necessary for the proper performance of FDA's functions, including whether the information has practical utility, and contended that eliminating the collection of information would minimize the burden on respondents.

Specifically, the comment suggested that FDA should ''eliminate unnecessary work'' related to requests for categorical exclusions for actions on certain investigational new drug applications (INDs). Section 25.31 lists classes of actions that are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS. Section 25.31(e) lists an ''action on an IND'' as one of these classes of actions. The comment proposed that § 25.31(e) be amended as follows: ''Action on INDs where the drug or biologic product is derived from wild plants or animals. Action on other types of INDs do not require a claim for a categorical exclusion.'' The comment proposed that categorical exclusions should be automatically granted for actions on INDs where the drug or biologic products are not derived from wild plants or animals.

The comment proposed this amendment to § 25.31(e) for the following reasons, each of which suggests that claims for categorical exclusion for action on an IND have little practical utility and amending § 25.31(e) as proposed represents a way to minimize the burden of the collection of information:

1. FDA's guidance document entitled ''Environmental Assessment of Human Drug and Biologics Applications'' (July 1998) states: ''INDs generally involve relatively small quantities of a drug or biologic product and treatment of a limited number of patients. Many INDs never result in the filing of an NDA or application for marketing approval of a biologic product, which would allow for the wide-spread commercial sale of the product. CDER and CBER will evaluate INDs on a case-by-case basis where the drug or biologic product is derived from wild plants or animals to determine whether the extraordinary circumstance provision in § 25.21 is invoked.'' (See section III.C.3.b.ii of the guidance document).

2. Pharmaceutical companies have been providing claims for categorical exclusion for action on an IND since the early 1990's for active pharmaceutical ingredients (APIs) in all therapeutic classes, and the companies have no indication that FDA has used these claims as the basis for denials pertinent to potential environmental impact as described under NEPA.

3. Usage of an API under an IND is ''site limited and time bounded,'' indicating that ''the potential for patient excretion of an API to the environment is extremely limited.''

4. The potential risk from pharmaceuticals in the environment pertains to long-term, chronic exposure, and usage of an API under an IND will not result in the type of exposure widely accepted as being of potential environmental concern. The comment also stated that prior to marketing approval of an API, FDA will have the opportunity to review potential environmental impact through its EA requirements.

5. The comment concluded that amending § 25.31(e) as proposed would have ''eliminated work on up to 1933 categorical exclusions (15,464 hours) for INDs in 2005 that ultimately had no practical utility.''

FDA appreciates the comment requesting that § 25.31(e) be amended so that categorical exclusions could be automatically granted for actions on INDs where the drug or biologic products are not derived from wild plants or animals. The purpose of the March 29, 2006, **Federal Register** notice and this notice, however, is to afford an opportunity for comment on the information collection requirements and burden estimates for part 25, and to request that OMB extend approval for that collection. Because the comment requests a rulemaking change, we have forwarded it to the office in each center that is responsible for the information collection requirements in part 25 so that the comment may be considered for any future amendments to the regulations.

FDA estimates the burden of this collection of information as follows:

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 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 2005, FDA received 1,933 INDs from 1,517 sponsors, 114 NDAs from 94 applicants, 2,682 supplements to NDAs from 293 applicants, 777 ANDAs from 161 applicants, and 4,318 supplements to ANDAs from 219 applicants. FDA estimates that it receives approximately 9,813 claims for categorical exclusions as required under § 25.15(a) and (d), and 11 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[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
25.15(a) and (d)	2,284	4.32	9,813	8	78,504
25.40(a) and (c)	11	1	11	3,400	37,400
Total					115,904

[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 for 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. From 2003 to 2005, FDA received an annual average of 88 industry submissions. FDA estimates that it received an annual average of 57 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, 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[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
25.15(a) and (d)	57	1.4	80	3	240
25.40(a) and (c)	31	1.3	39	210	8,190
Total					8,430

[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), premarket approvals (original premarket approval applications (PMAs) and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2005, FDA received 282 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). Based on information provided by less than 10 sponsors, FDA estimates that it takes approximately less than 1 hour to prepare a claim for a categorical exclusion and an unknown number of hours to prepare an EA.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
25.15(a) and (d)	47	6	282	1	282
25.40(a) and (c)	0	0	0	0	0
Total					282

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

Estimated Annual Reporting Burden for Biological Products

Under 21 CFR 312.23(a)(7)(iv)(e) and 601.2(a), IND and biologics license applications (BLAs) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2005, FDA received 565 INDs from 426 sponsors, 27 BLAs from 12 applicants, and 737 BLA supplements to license applications from 205 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 666 claims for categorical exclusion as required under § 25.15(a) and (d), and 2 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim for categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
25.15(a) and (d)	459	1.45	666	8	5,328
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,128

[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), NADAs and ANADAs, § 514.8(a)(1) supplemental NADAs and ANADAs, § 511.1 (b)(10) investigational new animal drug applications (INADs), § 570.35 (c)(1)(viii) generally recognized as safe (GRAS) affirmation petitions, 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 2005, the Center for Veterinary Medicine (CVM) has received approximately 421 claims for categorical exclusion as required under § 25.15(a) and (d), and 14 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors/applicants approximately 8 hours to prepare a claim for a categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
25.15(a) and (d)	134	3.9	421	8	3,368
25.40(a) and (c)	12	1.6	14	2,160	30,240
Total					33,608

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

Based on information provided by industry, FDA estimates that the combined annual total burden hours for all centers is 170,352.

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8025 Filed 9–21–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0380]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices-Foreign Letters of Approval

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for firms that intend to export certain unapproved medical devices.

DATES: Submit written or electronic comments on the collection of information by November 21, 2006.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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.

Export of Medical Devices-Foreign Letters of Approval (OMB Control Number 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

FDA uses the written authorization from the foreign country or the certification from a responsible company official in the United States to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

FDA estimates the reporting burden of this collection of information as follows: