the applications are received on or before the deadline time and date.

Applications hand-carried by applicants, applicant couriers, or other representatives of the applicant or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m. at: OCS Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22202 and labeled: Application for Compassion Capital Fund Demonstration Program. Applicants are cautioned that express/overnight mail services may not always deliver as agreed.

ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

Late applications. Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

Extension of deadlines. ACF may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, when there is widespread disruption of the mail service, or for other disruptions of services, such as a prolonged blackout, that affect the public at large. An unfortunate occurrence that affects an applicant is not considered adequate justification for an extension. A determination to waive or extend deadline requirements rest with ACF's Chief Grants Management Officer.

Dated: June 20, 2003.

Curtis L. Coy,

Deputy Assistant Sectretary for Administration.

[FR Doc. 03–16076 Filed 6–25–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0085]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 July 28, 2003.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (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—Part 25 (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 (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 at 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.

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 DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,031	4.32	8,773	8	70,184
25.40(a) and (c)	22	1	22	3,400	74,800
Total					144,984

[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 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 FOODS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	56	1.6	89	4	356
25.40(a) and (c)	18	1.7	31	210	6,510
Total					6,866

[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 (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 1998, FDA received 568 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 Response	Total Burden Hours
25.15(a) and (d)	94	6	564	1	564
25.40(a) and (c)	0	0	0	0	0
Total					564

[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 2001, FDA received 535 INDs from 376 sponsors, 80 BLAs from 22 applicants, and 837 BLA supplements to license applications from 168 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 699 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 Response	Total Burden Hours
25.15(a) and (d)	415	1.68	699	8	5,592
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,392

[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 § 514.1(b)(14) (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, 21 CFR 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. Since the last OMB approval of these collections of information, FDA's Center of Veterinary Medicine has received approximately 547 claims for categorical exclusion as required under § 25.15(a) and (d), and 19 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 Response	Total Burden Hours
25.15(a) and (d)	139	3.9	542	8	4,336
25.40(a) and (c)	14	1.4	19	2,160	41,040
Total					45,376

[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 burden for the environmental impact considerations—part 25 is as follows:

TABLE 6.—ESTIMATED ANNUAL REPORTING BURDEN FOR ALL CENTERS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,735	17.5	10,768	29	81,032
25.40(a) and (c)	56	5.1	74	9,199	129,150
Total					210,182

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

In the **Federal Register** of March 17, 2003 (68 FR 12702), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: June 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16107 Filed 6–25–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0066]

Agency Information Collection Activities; Announcement of OMB Approval; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 2003 (68 FR 22388), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to,