TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,886	652	2,533,355	.14	354,669

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

In the**Federal Register** of March 22, 2000 (65 FR 15340), the agency requested comments on the proposed collections of information. No comments were received.

Dated: June 22, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–16396 Filed 6–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0836]

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: Submit written comments on the collection of information by July 31, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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 FDA's regulation ''Environmental Impact Considerations'' (part 25).

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.

FDA's NEPA regulations are at part 25. All applications or petitions requesting agency action require the submission of an Environmental Assessment (EA) or a claim of categorical exclusion. Section 25.15(a) and (d) specify the procedures for submitting to FDA a claim for a categorical exclusion (certain classes of FDA-regulated actions have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS). Section 25.40(a) and (c) specify the content requirements for EA's 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 (when not eligible for categorical exclusion) 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** notice 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. When the agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact (FONSI).

I. Estimated Annual Reporting Burden for Human Drugs

Under 21 CFR 312.23(a)(7)(iv)(*e*), 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 1998, FDA received 2,427 IND's from 1,874 sponsors, 129 NDA's from 80 applicants, 2,500 supplements to NDA's from 238 applicants, 345 ANDA's from 101 applicants, and 3,713 supplements to ANDA's from 165 applicants. FDA estimates that it receives approximately 9,094 claims for categorical exclusions as required under § 25.15(a) and (d), and 20 EA's 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)	2,039	4.46	9,094	8	72,752
25.40(a) and (c)	20	1	20	3,400	68,000
Total					140,752

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

II. Estimated Annual Reporting Burden for Human Foods

Under 21 CFR 71.1, 170.39, and 171.1, food additive petitions, color additive petitions, and requests for exemption from regulation as a food additive must contain a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. In 1998, FDA received 57 food additive petitions, 9 color additive petitions, and 26 threshold of regulation exemption requests. FDA estimates that it received approximately 80 claims of categorical exclusions as required under § 25.15(a) and (d), and 12 EA's as required under § 25.40(a) and (c). FDA estimates that it takes petitioners or requesters 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)	44	1.8	8.0	8	640
25.40(a) and (c)	11	1.1	12	210	2,520
Total					3,160

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

The Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a premarket notification process as the primary method for authorizing a new use of a food additive that is a food contact substance. Section 409(h)(6) of the act defines a food contact substance as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in food. Under the notification process, FDA must be notified at least 120 days prior to the marketing of a food contact substance. If FDA does not object within 120 days to the use of a food contact substance that is the subject of a notification, the substance may be legally marketed for the notified use. FDA expects that the majority of new uses of food contact substances that will be the subject of premarket notifications would previously have been regulated under the food additive petition process or exempted from the requirement of a regulation under the threshold of regulation process. FDA has provided in a separate **Federal Register** notice an opportunity for public comment on the collection of information associated with the premarket notification program, including environmental information requirements (64 FR 61648, November 12, 1999).

III. Estimated Annual Reporting Burden for Medical Devices

Under 21 CFR part 814, premarket approvals (original PMA's and supplementals) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 1998, FDA received 568 claims (original PMA's and supplementals) for categorical exclusions as required under § 25.15(a) and (d), and 0 (zero) EA's 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	568	1	568
25.40(a) and (c)	0	0	0	0	0
Total					568

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

IV. Estimated Annual Reporting Burden for Biological Products

Under 21 CFR 312(a)(7)(iv)(*c*) and 601.2(a), IND and biologics license applications must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 1998, FDA received 492 IND's from 278 sponsors, 78 license applications from 20 applicants, and 903 supplements to license applications from 190 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 receives approximately 660 claims for categorical exclusion as required under § 25.15(a) and (d), and 2 EA's 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.

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)	317	2	660	8	5,280
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,080

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

V. Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14) new animal drug applications (NADA's) and abbreviated new animal drug application (ANADA), 514.8(a)(1) supplemental NADA's and ANADA's, 511.1(b)(10) investigational new animal drug applications, 570.35(c)(1)(viii) generally recognized as safe, affirmation petitions, and 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. Since the last OMB approval of the subject collections of information, the Center for Veterinary Medicine has received approximately 545 claims for categorical exclusions as required under § 25.15(a) and (d), and 32 EA's 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 approximately 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)	194	2.8	545	8	4,360
25.40(a) and (c)	29	1.1	32	2,160	69,120
Total					73,480

[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 are 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)	2,688	17.06	10,875	33	83,600
25.40(a) and (c)	62	4.02	66	9,170	146,440
Total	2,750	21.08	10,941	9,203	230,040

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

In the **Federal Register** of March 13, 2000 (65 FR 13405), the agency requested comments on the proposed collections of information. No comments were received.

Dated: June 22, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–16398 Filed 6–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13 and 14, 2000, 8:30 a.m. to 5 p.m.

Location: CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jayne E. Peterson or Tony A. Slater, Jr., Center for Drug Evaluation and Research (CDER) (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13, 2000, the committee will review five drug products for inclusion on a list of drug products that cannot be compounded because they have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see 21 CFR 216.24 (64 FR 10944, March 8, 1999)) whereby FDA amended its regulations to include such a list of drug products). In the **Federal Register** of January 4, 2000 (65 FR 256), FDA published a proposed rule amending these regulations to add two drug products to the list: (1) Aminopyrine (all drug products containing aminopyrine) and (2) astemizole (all drug products containing astemizole). In addition to these two drug products, the committee will review the following three drug products: (1) Grepafloxacin (all drug products containing grepafloxacin), (2) troglitazone (all drug products containing troglitazone), and (3) cisapride (all drug products containing cisapride). Beginning at approximately 10 a.m., and continuing on July 14, 2000, at approximately 8:30 a.m., the committee will discuss and provide FDA with advice about drug products that present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of those drug products.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the committee. Written submissions may be made to the contact person by July 3, 2000. On July 13, 2000, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On July 14, 2000, oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the July 13 and 14, 2000, Pharmacy Compounding Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Pharmacy Compounding Advisory Compounding Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 20, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–16397 Filed 6–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1313]

Draft Guidance for Industry on How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#86) entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' in the Center for Veterinary Medicine (CVM). This draft guidance is neither final nor is it in effect at this time. The draft guidance document is intended to provide guidance to new animal drug sponsors (sponsors) on how to submit a notice of final disposition of animals not intended for immediate slaughter (NFDA) as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This draft guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by August 28, 2000 to ensure their adequate consideration in preparation of the final document. Submit written comments on the information collection requirements by August 28, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.

Copies of the draft guidance document entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' may be obtained on the