such as agency promotion brochures, slides, tapes, film clips, minutes of meetings, survey instruments or articles of incorporation.

G. Paperwork Reduction Act of 1995 (P.L. 104–13)

The Uniform Project Description information collection within this announcement is approved under the Uniform Project Description (0970–0139), Expiration Date 10/31/2000.

Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(Federal Catalog of Domestic Assistance Number 93.631 Developmental Disabilities—Projects of National Significance)

Dated: March 1, 2000.

Sue Swenson,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 00–6107 Filed 3–10–00; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0836]

Agency Information Collection Activities: Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing applications for FDA approval to market a new drug.

DATES: Submit written comments on the collection of information by May 12, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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: (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.

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 **Federal Register** notice 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. 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)(*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 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 and 170.39, 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 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 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)	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 (FDAMA) (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, 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 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

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

21 CFR Section	No. of <Respondents	Annual <Frequency per <Response	Total Annual Responses	Hours per <Response	Total Burden Hours
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 312.23(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 applications (ANADA's), 514.8(a)(1) supplemental NADA's and ANADA's, 511.1(b)(10) investigational new animal drug applications (INADA's), 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 § 25.31 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.—ENTIRE TOTAL 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 cost associated with this collection of information.

Dated: March 6, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–5969 Filed 3–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medwatch/MDR/FDA Website Navigation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing the following public meeting: Medwatch/Medical Device Reporting (MDR)/FDA Website Navigation. The topics to be discussed are the Medwatch Program, medical device reporting, and the navigation of the FDA website. This public meeting is intended to familiarize the attendees with the Medwatch Program, provide information on the regulations associated with the mandatory medical device reporting system, and furnish training on the navigation of the FDA website.

Date and Time: The public meeting will be held on April 7, 2000, from 9 a.m. to 12 noon.

Location: The public meeting will be held at the Mercy Medical Center Auditorium, 2175 Rosaline Ave., Redding, CA 96049.

Contact: Mary E. Taylor, Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070, 510–337–6888, FAX 510–337–6708, e-mail: mtaylor1@ora.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by March 30, 2000.

If you need special accommodations due to a disability, please contact Mary E. Taylor at least 7 days in advance.

Dated: March 6, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–5968 Filed 3–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Children's Hospital Graduate Medical Education Program—New

Public Law Number 106–129 amended the Public Health Service Act to establish a new program to support graduate medical education (GME) in children's hospitals. The provision authorizes payments in FY 2000 and FY 2001 for direct and indirect expenses associated with operating approved GME programs. Section 340E(c)(1) states that the amount determined under this subsection for payments for direct medical expenses for a fiscal year is equal to the product of: (A) The updated per resident amount as determined, and (B) the average number of FTE residents in the hospital's approved graduate medical residency training programs as determined under section 1886(h)(4) of the Social Security Act during the fiscal year. The statute directs the Secretary to take into account factors identified in section 340E(b)(1)(B) and 340E(d)(2)—case mix, number of FTE residents, treatment of more severely ill patients and the additional costs related to teaching residents.

Administration of the Children's Hospital Graduate Medical Education Program relies on the reporting of the number of full-time equivalent residents in applicant children's hospital training programs to determine the amount of direct and indirect expense payments to participating children's hospitals. Indirect expense payments will also be derived from a formula that requires the reporting of case mix index information from participating children's hospitals.

Hospitals will be requested to submit such information in an annual application. The statute also requires reconciliation of the estimated numbers of residents with the actual number determined after the close of the fiscal year. Participating children's hospitals would be required to complete an adjusted report to correct such information on an annual basis.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	No. of respondents	Responses per respondent	Total responses	Hrs. per response	Total hour burden
Form A	48	1	48	28	1,344