Estimated Annual Reporting Burden					
Type of Response[1]	No. of Respondents[2]	Annual Frequency per Response[3]	Total Annual Responses[4]	Hours per Response	Total Hours
NDA[5]	162	22.9	3,715	40	148,600
ANDA[6] and AADA[7]	350	18.6	6,517	40	260,680
ELA[8] and PLA[9]	391	4.9	1,905	40	76,200
Total Burden Hours					485,480

There are no capital costs or operating and maintenance costs associated with this collection.
[1] Includes original applications and their amendments and supplemental applications
[2] Number of sponsors submitting applications during fiscal year (FY) 95
[3] Average number of applications submitted per sponsor
[4] Total applications submitted during FY 95
[5] New Drug Application (includes applications for new antibiotic drugs)
[6] Abbreviated New Drug Application
[7] Abbreviated Antibiotic Drug Application
[8] Establishment License Application
[9] Product License Application

In FY 95, CDER received a total of 10,232 submissions and CBER received 1,905 submissions that would require use of this application form. FDA estimates that 40 hours would be needed for an industry regulatory affairs specialist to fill out the harmonized form, collate the documentation, and submit the application to CDER or CBER.

Dated: March 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6360 Filed 3–12–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1996. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologicals granted orphan-drug designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Peter L. Vaccari, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0983.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologicals. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologicals, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses.

The list that is the subject of this notice consists of designated orphan drugs and biologicals through December 31, 1996, and, therefore, brings the April 22, 1996 (61 FR 17708) publication up to date. This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this document.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: March 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6357 Filed 3–12–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0283]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding Regulations under the Federal Import Milk Act, has been approved by the Office of Management and Budget (OMB), under the Paperwork Reduction

Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 24, 1996 (61 FR 50030), the agency announced that the proposed information collection had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the information collection and assigned OMB control number 0910–0212. The approval expires on October 31, 1999. Under 5 CFR 1320.5(b), 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.

Dated: March 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6361 Filed 3–12–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 17, 1997.

Time: 9:30 a.m.

Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Sheri L. Schwartzback, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–4843.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 25, 1997.

Time: 1 p.m.

Place: Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Jean K. Paddock, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–4868.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 97–6287 Filed 3–12–97; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

National Institute of Environmental Health Sciences; Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods, Now Available

The publication Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods, NIH Publication 97–3981 is now available and may be obtained as described in this notice.

Background

The National Institutes of Health Revitalization Act of 1993 (Pub. L. 103–43, Section 1301) directed the National Institute of Environmental Health Sciences of the National Institutes of Health (NIEHS/NIH) to ''(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use'' (Appendix F).

In response to these mandates, NIEHS established an ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (the Committee) in 1994 to develop a report recommending criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to Federal agencies and the scientific community. The following Federal regulatory and research agencies and organizations participated in this effort:

Consumer Product Safety Commission
Department of Agriculture
  Agriculture Research Service
  Animal and Plant Health Inspection Service
Department of Defense
Department of Energy
Department of Health and Human Services
  Agency for Toxic Substances and Disease Registry
  Food and Drug Administration
  National Institute for Occupational Safety and Health/CDC
  National Institute of Health
  National Cancer Institute
  National Institute of Environmental Health Sciences
  National Library of Medicine
  Office of Laboratory Animal Research
Department of the Interior
Department of Labor
  Occupational Safety and Health Administration
Department of Transportation
  Research and Special Programs Administration
Environmental Protection Agency

The Committee met initially in September 1994, and then monthly or bimonthly until completion of the report in October 1996. The Committee interpreted its charge as the development of general criteria and processes for the validation and regulatory acceptance of new and revised toxicological test methods.

The specific goals of this Report are to:

- Communicate the criteria and procedures that Federal agencies should employ in considering new and revised test methods,
- Encourage the development of new and revised test methods that will provide for improved assessment of the potential toxicity of agents to human health and other organisms in the environment,
- Provide effective guidance for scientists for the validation and evaluation of new and revised test methods,
- Contribute to the increased likelihood of regulatory acceptance of scientifically valid new and revised test methods,
- Encourage the use of validated and accepted new and revised test methods,
- Encourage, when scientifically feasible, the reduction and refinement of animal use in testing and the replacement of animal methods with non-animal methods or of animal species with phylogenetically lower species.

In developing the initial draft report, the Committee considered information obtained from the following sources: (1) A questionnaire completed by each agency on their criteria and processes for test method validation and acceptance, (2) public comments submitted in response to a Federal Register notice published December 7,