(1) Foster coordination among all governmental agencies, academic bodies and community groups that conduct or support Fetal Alcohol Syndrome (FAS) and Fetal Alcohol Effect (FAE) research, programs and surveillance; and

(2) To otherwise meet the general needs of populations actually or potentially impacted by FAS and FAE.

Matters to be Discussed: Agenda items include: a review of the September 2002 Task Force Recommendations and the activities undertaken by Federal and non-governmental agencies and organizations in response to the recommendations; the identification of priority areas for the current Task Force; and the reconvening of the Research working group and the Services and Public Awareness working group. Additional agenda items include: updates from Task Force members on current initiatives; an update on activities from the Interagency Coordinating Committee on Fetal Alcohol Syndrome, the CDC and other Federal agencies; reports from Task Force liaison organizations; future topics, and scheduling the next meeting.

Agenda items are subject to change as priorities dictate.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

For Further Information Contact: R. Louise Floyd, DSN, RN, Designated Federal Official, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, NE, (E–86), Atlanta, Georgia 30333, telephone 404/498–3923, fax 404/498–3550.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the CDC and ATSDR.

Dated: May 28, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–12675 Filed 6–3–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates: 9 am—5 pm, June 23, 2004. 8 am—5 pm, June 24, 2004.

Place: Atlanta Marriott Century Center, 2000 Century Boulevard, NE., Atlanta, Georgia 30345–3377.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. § 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The Agenda will include discussions on influenza; IOM report on autism and vaccines; an update on Hepatitis A vaccine; recommended childhood and adolescent immunization schedules; PCV7 shortage; discussion on meningococcal conjugate vaccine; smallpox pregnancy registry outcomes; pertussis; working group and departmental updates.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Demetria Gardner, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE, (E–61), Atlanta, Georgia 30333, telephone 404/639–8096, fax 404/639–8616.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 27, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–12677 Filed 6–3–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0360]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 19, 2004 (69 FR 7753), 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, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0459. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12684 Filed 6–3–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0244]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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 allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for manufacturers of type A medicated articles.

DATES: Submit written or electronic comments on the collection of information by August 3, 2004.

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, 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 reinstatement 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.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226 (OMB Control Number 0910–0154)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including type A medicated articles. A type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A type A medicated article is intended solely for use in the manufacture of another type A medicated article or a type B or type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B). Under part 226, a manufacturer is required to establish, maintain, and retain records for type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing) and product distribution. This information is needed so that FDA can monitor drug usage and possible misformulation of type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of type A medicated articles are adequate to assure that their medicated articles meet the requirements of the Act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

The respondents for type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs, and commercial feed mills.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475
226.115	115	10	1,150	0.5	575
Total					157,550

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

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: May 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12685 Filed 6–3–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0481]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions

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 (the PRA).

DATES: Fax written comments on the collection of information by July 6, 2004.

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

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.

Food Additive Petitions—21 CFR Part 571

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348 (a)), provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the act specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but attempt to explain the requirements and provide a standard format for submission to speed the processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 572, 573, and 580. The labeling regulations are considered by FDA to be cross referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

In the **Federal Register** of November 12, 2003 (68 FR 64110), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Annual Frequency	Per Response	Total Annual Responses	Hours per Response
571.1(c) moderate category	1	1	1	1,800	1,800
571.1(c) complex category	1	1	1	6,000	6,000
571.6	2	2	4	1,300	5,200
Total	4	4	6	9,100	13,000

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

Dated: May 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12686 Filed 6–3–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; Graduate Student Training Programs Application Correction Notice

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) previously published a notice soliciting pubic comment on the proposed data collection project entitled, ''Graduate Student Training Program Application'' in the **Federal Register** on May 5, 2004 (69 FR 25132–25133). In the notice we errantly identified the data collection project as an extension. However, the data collection project is a revision, not an extension. We apologize for any confusion this error may have caused you.

Dated: May 28, 2004.

Michael M. Gottesman,

Deputy Director for Intramural Research, National Institutes of Health.

[FR Doc. 04–12665 Filed 6–3–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose