activities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include: Health consultations and public health assessments at sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public.

This draft document, Public Health Reviews of Hazardous Waste Thermal Treatment Technologies, will assist in the Agency's critical mission to reduce and prevent exposures and adverse health outcomes from exposure to hazardous substances. The document provides technical guidance for Agency staff who review thermal treatment technologies to evaluate the potential public health effects associated with the use of incinerators or thermal desorbers to treat hazardous wastes. This document contains detailed technical guidance to promote consistency among Agency staff during evaluations of thermal treatment facilities. People who do not have technical experience and knowledge of thermal technologies may find it difficult to understand.

This draft, Public Health Reviews of Hazardous Waste Thermal Treatment Technologies, is available for public comment so the Agency can benefit from public review and input before finalizing the document. This **Federal Register** notice announces that this draft document is available for public comment.

Dated: March 19, 2001.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 01–7235 Filed 3–22–01; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee Resettlement Program Estimates: CMA, ORR–1.

OMB No. 0970–0030.

Description: ORR reimburses, to the extent of available appropriations, certain non-Federal costs for the provision of cash and medical assistance to refugees, along with allowable expenses in the administration of the Refugee Resettlement Program. ORR needs sound State estimates of likely expenditures for refugee cash, medical, and administrative (CMA) expenditures so that it can anticipate Federal costs in upcoming quarters. If Federal costs are anticipated to exceed budget allocations, ORR must take steps to reduce Federal expenses, such as limiting the number of months of eligibility for Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA).

To meet the need for reliable State estimates of anticipated expenses, ORR has developed a single-page form in which States estimate the average number of recipients for each category of assistance, the average unit cost over the next 12 months and the expense for the overall administration of the program. This form, the ORR–1 (formerly Form FSA–601) must be submitted prior to the beginning of each Federal fiscal year. Without this information, ORR would be out of compliance with the intent of its legislation and otherwise unable to estimate program costs adequately.

In addition, the ORR–1 serves as the State's application for reimbursement of its CMA expenses. Submission of this form is thus required by section 412(a)(4) of the Immigration and Nationality Act which provides that ''no grant or contract may be awarded under this section unless an appropriate proposal and application * * * are submitted to, and approved by, the appropriate administering official.''

Respondents: State, Local or Tribal Govt.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1	48	1	.5	24
Estimated Total Annual Burden Hours				24

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 19, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–7187 Filed 3–22–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0114]

Agency Information Collection Activities; Proposed Collection; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

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 FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision. Where a patented product must receive FDA approval before marketing is permitted, the Office of Patents and Trademarks may add a portion of the FDA review time to the term of a patent. Petitioners may request reductions in the regulatory review time if FDA marketing approval was not pursued with ''due diligence.''

DATES: Submit written or electronic comments on the collection of information by May 22, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. 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 L. 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.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—Part 60 (21 CFR Part 60) (OMB Control No. 0910–0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patents's term may be consumed during this review, which diminishes the value of the patent. In enacting 35 U.S.C. 156, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under § 60.24, revision of the length of the regulatory review period, or may petition under § 60.30 to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.'' The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40, request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, five requests for revision of the regulatory review period have been submitted under § 60.24. One regulatory review period has been altered. No due diligence petitions have been submitted to FDA under § 60.30, and consequently there have been no requests for hearings under § 60.40 regarding the decisions on such petitions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	1	1	1	100	100
60.30	0	0	0	0	0

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					100

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

Dated: March 19, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–7243 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1033]

Agency Information Collection Activities; Announcement of OMB Approval; Information Program on Clinical Trials for Serious and Life-Threatening Diseases

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'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 9, 2000 (65 FR 67385), 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 0910–0116. The approval expires on March 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: March 19, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–7244 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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: Pediatric Subcommittee of the Anti-Infective Drugs 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 April 23, 2001, 8 a.m. to 5:30 p.m. and on April 24, 2001, 8 a.m. to 3 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD 20857.

Contact: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 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 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 23, 2001, beginning at 8 a.m., the subcommittee will discuss issues in drug development for pediatric patients with chronic hepatitis C. Beginning at 3:30 p.m., the agency will provide an update to the subcommittee as to recent efforts to ensure adequate labeling and proper pediatric use of therapies. On April 24, 2001, the subcommittee will discuss issues involved in designing clinical trials to study anti-muscarinics for drooling in children with cerebral palsy and other neurologic diseases, as well as the ethical issues involved in performing studies with children having special needs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 13, 2001. On April 23 and 24, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 13, 2001, 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.

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

Dated: March 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–7186 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and