authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 20, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–31604 Filed 11–25–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

State Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children new and competing Grantees Pre-application Workshop

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: State Childhood Lead Poisoning Prevention and Surveillance of Blood Lead Levels in Children new Grantees Pre-application workshop.

Time and Date: 2 p.m.–5 p.m., January 31, 1999.

Place: Holiday Inn SunSpree Resort and Conference Center, 715 South Gulfview Boulevard, Clearwater Beach, Florida, 33767, telephone 813–447–9566.

Status: Open to the public, limited only by space available. The meeting room accommodates approximately 100 people.

Purpose: The purpose of this meeting is to provide a forum for childhood lead poisoning prevention coordinators to address issues and concerns relating to the FY99 program announcement and application process.

Matters to be Discussed: Agenda items include FY99 program announcement and processes related to the completion of applications for FY99 funds.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Claudette Grant-Joseph, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–42, Atlanta, Georgia 30341–3724, telephone 770/488–7330.

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 Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 20, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–31605 Filed 11–25–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Workshop on the Potential for Transfusion-Transmission of Tickborne Agents

The Centers for Disease Control and Prevention (CDC) announces an open meeting concerning the potential for transfusion-transmission of tickborne agents.

Name: Workshop on the Potential for Transfusion-Transmission of Tickborne Agents.

Times and Dates: 10 a.m.–5 p.m., January 14, 1999. 8:30 a.m.–12 p.m., January 15, 1999.

Place: Holiday Inn Hotel and Conference Center, 130 Clairmont Avenue, Decatur, Georgia 30030.

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

Purpose: The objectives of this meeting are to review current information on tickborne pathogens and their potential for transmission by blood transfusion; identify information gaps and research priorities; and identify approaches to reduce the risk of transfusion-related infections from tickborne agents.

Matters To Be Discussed: Agenda items will include:

1. Epidemiology of Major Tickborne Diseases
2. Mechanics of Transmission to the Human Host
3. Pathogenesis, Clinical Disease, and Persistence of the Organism in Human Host
4. Persistence, Detection, Inactivation of Organisms in Blood and Blood Products
5. Studies in Donors and Recipients
7. Department of Defense Perspective/Special Studies
8. Blood Banking Perspective of Transfusion Transmission of Tickborne Agents
9. Panel Discussion

Other agenda items include announcements/introductions; question and answer sessions; and consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Tanya Mercer, Viral & Rickettsial Zoonoses Branch, NCID, CDC, 1600 Clifton Road, m/s G–13, NE, Atlanta, Georgia 30333, telephone 404/639–1075, fax 404/639–4436.

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 Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 20, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–31606 Filed 11–25–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Early Head Start Evaluation Father Study.

OMB No.: 0970–0169.

Description: The Head Start Reauthorization Act of 1994 established a special initiative creating funding for services for families with infants and toddlers. In response the Administration on Children, Youth and Families (ACYF) designed the Early Head Start (EHS) program. In September 1995, ACYF awarded grants to 68 local programs to serve families with infants and toddlers. ACYF has awarded grants to additional programs, totaling more than 290.

EHS programs are designed to produce outcomes in four domains: (1) Child development, (2) family development, (3) staff development, and (4) community development. The Reauthorization required that his new initiative be evaluated. To study the effect of the initiative, ACYF awarded a contract through a competitive

procurement to Mathematics Policy Research, Inc. (MPR) with a subcontract to Columbia University's Center for Young Children and Families. The evaluation will be carried out from October 1, 1995 through March 30, 2002. Data collection activities that are the subject of this **Federal Register** notice are intended for the fourth phase of the EHS evaluation. The sample for the assessments will be approximately 1,144 fathers from the 3,000 EHS sample families, whose mothers and infants/toddlers are participating in the study (see OMB #0970–0143) in 13 of the EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The 36-month father assessments will be conducted through personal interviewing, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to better understand the roles of fathers and father-figures with their children and in the EHS program.

Respondents: Fathers or father-figures of children whose families are in the EHS national evaluation sample (both program and control group families).

ANNUAL BURDEN ESTIMATES

Instrument	Estimated number of respondents	Number of responses per respondent	Average burden hours per respondent	Total burden hours
36-month father interview	89	1	1.0	89
36-month interview and videotaping protocol	74	1	1.3	96
36-month abbreviated interview and videotaping protocol	30	1	1.05	32
Estimated Total Annual Burden: 217.				

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: November 20, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–31566 Filed 11–25–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0480]

Determination of Regulatory Review Period for Purposes of Patent Extension; Tasmar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Tasmar and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Tasmar® (tolcapone). Tasmar® is indicated for use as an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Tasmar® (U.S. Patent No. 5,236,952) from Hoffman–La Roche, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 15, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Tasmar® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Tasmar® is 2,618 days. Of this time, 2,014 days occurred during the testing phase of the regulatory review period, while 604 days occurred during the