DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–0990–0263]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#1 *Type of Information Collection Request:* Extension of Currently Approved Collection;

Title of Information Collection: Protection of Human Subjects Assurance Identification/ Institutional Review Board (IRB) Certification/ Declaration of Exemption;

Form/OMB No.: OS–0990–0263;

Use: The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)].

Frequency: Reporting on occasion;

Affected Public: Federal, State, local, or tribal governments, business or other for-profit, not-for-profit institutions and individuals or households;

Annual Number of Respondents: 5,000; Total Annual Responses: 166,667;

Average Burden per Response: 0.25 hours;

Total Annual Hours: 41,667;

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at *http://www.hhs.gov/oirm/infocollect/pending/* or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *naomi.cook@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the OS Paperwork Clearance Officer designated at the following address: Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (0990–0263), Room 531–H, 200 Independence Avenue, SW., Washington, DC 20201.

Dated: May 11, 2005.

Robert E. Polson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 05–10004 Filed 5–18–05; 8:45 am]

BILLING CODE 4168–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Meeting

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 meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Antimalarial Drug Resistance and Prevention of Malaria During Pregnancy CI05–061, Linkage of International Collaboration and Research Programs for Prevention and Control of Malaria, CI–05–062 and Comparisons of Community with Facility Management of Malaria and Pneumonia in Rural Tanzania, CI05–064.

Times and Dates: 1 p.m.–3:30 p.m., June 15, 2005 (Closed).

Place: Teleconference.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Preventing Maternal and Neonatal Bacterial Infections in Developing Settings with a High Prevalence of HIV: Antimalarial Drug Resistance and Prevention of Malaria During Pregnancy CI05–061, Linkage of International Collaboration and Research Programs for Prevention and Control of Malaria, CI–05–062 and Comparisons of Community with Facility Management of Malaria and Pneumonia in Rural Tanzania, CI05–064.

FOR FURTHER INFORMATION CONTACT: Trudy Messmer, Ph.D., Scientific Review Administrator, National Center for Infectious Diseases, CDC, 1600 Clifton Road NE., Mailstop C19, Atlanta, GA 30333, Telephone (404) 639–3770.

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 12, 2005.

Alvin Hall,

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

[FR Doc. 05–9987 Filed 5–18–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0389] (formerly 02D–0389)

Guidance for Industry on Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients.'' This document is intended to provide guidance on the types of toxicity information that FDA recommends be provided to the agency to support the use of new excipients in drug products. Previously, such information was not available to drug sponsors in a written document. This information should allow drug sponsors to determine if a potential new excipient is safe to use in drug products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug