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]

BILLING CODE 4163–18–P

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

Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

For the Center for Drug Evaluation and Research: Robert E. Osterberg, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2120, or

For the Center for Biologics Evaluation and Research: Mercedes A. Serabian, Center for Biologics Evaluation and Research (HFM–760), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6536.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients.'' This guidance addresses the safety testing of potential excipients to be used in pharmaceutical products. Not all excipients are inert substances; some have been shown to be potential toxicants. The Federal Food, Drug, and Cosmetic Act of 1938 (the act) was enacted after the tragedy of the elixir of sulfanilamide in 1937 in which an untested excipient was responsible for the death of many children who consumed the pharmaceutical. The act required manufacturers to perform safety testing of pharmaceuticals and submit new drug applications (NDAs) demonstrating safety before marketing. Since that time, the agency has become aware that certain other excipients used in commerce can cause serious toxicities in consumers of prescription and over-the-counter (OTC) drug products in the United States and other countries.

Some of the information used in developing this guidance was obtained during meetings involving the International Pharmaceutical Excipients Council, the United States Pharmacopeia, and the International Conference on Harmonisation. On October 2, 2002 (67 FR 61910), FDA announced the availability of a draft version of this guidance entitled ''Nonclinical Studies for Development of Pharmaceutical Excipients.'' A number of comments were received, and the agency considered them carefully as it finalized the guidance.

This guidance describes the types of toxicity data that the agency uses in determining whether a potential new excipient is safe for use in human pharmaceuticals. It discusses recommended safety evaluations for excipients proposed for use in OTC and generic drug products, and describes testing strategies for pharmaceuticals proposed for short-term, intermediate, and long-term use. It also describes recommended excipient toxicity testing for pulmonary, injectable, and topical pharmaceuticals.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on nonclinical studies for the safety evaluation of pharmaceutical excipients. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9957 Filed 5–18–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–21187]

Identity Security and Modernization of the Merchant Mariner Credential Statutes

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Coast Guard believes that identity verification is a critical element of port security, recognizing that we must know and trust those who are provided unescorted access to our port facilities and vessels. The Coast Guard will hold a public meeting to accept comments concerning the President's proposal to implement the recommendations of the 9/11 Commission Report in the area of Merchant Mariner Credentials and to modernize these statutes (hereinafter referred to as ''the proposal''). The proposal may be viewed in the docket for this notice. The Coast Guard also seeks written comments on the proposal.

DATES: The public meeting will be held on Friday, June 17, 2005, from 9 a.m. to 5 p.m. This meeting may close early if all business is finished. Members of the public who desire to make an oral statement may sign up on the day of the meeting. Written comments and related material must reach the Docket Management Facility on or before June 29, 2005.

ADDRESSES: The public meeting will be held in the Gallery Ballroom of the Arlington Hilton Hotel, 950 North Stafford Street, Arlington, VA 22203. Further directions regarding the location of the Arlington Hilton may be obtained by phoning (703) 528–6000.

You may submit written comments identified by Coast Guard docket number USCG–2005–21187 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Web Site: *http://dms.dot.gov.*

(2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.