Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: John Koerner, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5338.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of June 14, 2002 (67 FR 40950), the agency made available a draft guidance entitled ''S7B Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals'' and invited public comment. After considering the comments, the Safety Expert Working Group of the ICH made extensive changes to the document, including changes to the title of the draft guidance, the testing strategy, and the timing of nonclinical studies relative to clinical development.

In June 2004, the ICH Steering Committee agreed that a revised draft guidance entitled ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals'' should be made available for public comment. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance provides guidance on nonclinical assessment of the effects of pharmaceuticals on ventricular repolarization and proarrhythmic risk. The draft guidance describes a nonclinical testing strategy for assessing the potential of a test substance to delay ventricular repolarization and includes information concerning nonclinical assays and an integrated risk assessment.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 draft guidance. Submit a single copy of electronic comments or two paper copies of any 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 draft guidance and received comments may be seen 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/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: September 3, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–20564 Filed 9–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

The National Community Anti-Drug Coalition Institute Registry and Annual Survey—New—The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention has established the National Community Anti-Drug Coalition Institute through a grant to the Community Anti-Drug Coalitions of America (CADCA). The purpose of the Registry and Annual Survey is to collect and report on data which identify and describe the types of community coalitions across our Nation, and the activities in which they are involved. This information will help SAMHSA encourage and assist in the development of effective community coalitions and strategies designed to prevent illicit drug and underage alcohol and tobacco use. These data will also permit SAMHSA to address its responsibilities and measure performance as delineated in the HP2010 objective 26–23: to increase the number of communities using partnerships or coalition models to conduct comprehensive substance abuse prevention efforts.

To track progress in achieving this objective, SAMHSA will use these data

to develop a national inventory of anti-drug coalitions and partnerships that can be updated annually in order to determine the number of community anti-drug coalitions in operation. Based on the coalition literature and input from the field, the inventory will include information on important characteristics, such as operational status, organizational type, target population served, funding sources, geographic location, and major community sector involvement, including faith, business, school, service, and law sectors. The ''snowball'' method will be employed to obtain lists of local anti-drug coalitions who will be asked to complete the Web-based survey. The proposed project will yield an electronic directory, developed by experts, to describe the range of operational definitions of ''community anti-drug coalitions.'' The inventory will be based on a variety of typologies of coalitions and partnerships (including the coalitions who receive grants from the Drug Free Communities Support Program that will encompass the breadth of coalition activities. It is anticipated that the resulting electronic directory will be made available to the field through a Web-based database that will be managed, maintained, and updated by the Institute.

Once the data set is cleaned, a random sample of approximately ten percent of respondents will be selected to participate in a survey verification process. This verification will be conducted by telephone interview.

The annual burden associated with this survey is summarized in the following table.

	Number of respondents	Responses/ respondent	Burden/ response (hrs.)	Total burden hours
Annual Survey Questionnaire	7,500	1	1.0	7,500
Survey Verification	750	1	0.5	375
Total	7,500			7,875

Written comments and recommendations concerning the proposed information collection should be sent by October 13, 2004 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395–6974.

Dated: September 3, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 04–20597 Filed 9–10–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2004–19049]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Chemical Transportation Advisory Committee (CTAC) and its subcommittees will meet to discuss various issues relating to the marine transportation of hazardous materials in bulk.

DATES: CTAC will meet on Thursday, September 30, 2004, from 9 a.m. to 3:30 p.m. The Subcommittee on National Fire Protection Association 472 will meet on Wednesday, September 29, 2004 from 8:30 a.m. to 3 p.m. The Subcommittee on Hazardous Cargo Transportation Security will meet on Wednesday, September 29, 2004, from 3 p.m. to 4 p.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before September 23, 2004. Requests to have a copy of your material distributed to each member of the Committee should reach the Coast Guard on or before September 23, 2004.

ADDRESSES: CTAC will meet at U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC, in room 2415. Both the Subcommittee on National Fire Protection Association 472 and Hazardous Cargo Transportation Security will meet at Department of Transportation Headquarters, Nassif Building, 400 7th Street, SW., Washington, DC, in room 4438/4440. Send written material and requests to make oral presentations to Commander Robert J. Hennessy, Executive Director of CTAC, Commandant (G–MSO–3), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001 or e-mail: *CTAC@comdt.uscg.mil.* This notice is available on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Commander Robert J. Hennessy, Executive Director of CTAC, or Ms. Sara Ju, Assistant to the Executive Director, telephone 202–267–1217, fax 202–267–4570.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of the National Fire Protection Association 472 Subcommittee Meeting on September 29, 2004:

(1) Introduce Subcommittee members and attendees.

(2) Discuss results of meeting with the Technical Committee on Hazardous Materials Response Personnel of the National Fire Protection Association.

(3) Prepare draft chapter for possible incorporation of marine specific competencies into the National Fire Protection Association (NFPA) 472 Standard.

Agenda of the Hazardous Cargo Transportation Security Subcommittee Meeting on September 29, 2004:

(1) Introduce Subcommittee members and attendees.

(2) Discuss status of CTAC recommendations to the Coast Guard.

(3) Discuss future efforts of the Subcommittee.

Agenda of CTAC Meeting on Thursday, September 30, 2004:

(1) Introduce Committee members and attendees.

(2) Status report from the CTAC National Fire Protection Association 472 Subcommittee.

(3) Status report from CTAC Hazardous Cargo Transportation Security Subcommittee.

(4) Discussion of responsibilities and limitations of CTAC liaison to other advisory committees.

(5) Discussion of CTAC charter review workgroup.

(6) Presentation by CTAC reviewing recent marine casualties.