Regulation	Respondent	Number of applicants	Number of responses per applicant	Average Burden per Response (in minutes)
42 CFR 70.3	Traveler	2,000	1	15/60
	Attending physician	2,000	1	15/60
42 CFR 70.3	State Health Authority	8	250	6/60
42 CFR 70.4	The Master of a vessel or person in charge of a conveyance engaged in interstate traffic.	1,500	1	15/60
42 CFR 70.4	State or local Health authority	20	75	6/60
41 CFR 70.5	Traveler	3,750	1	15/60
	Attending physician	3,750	1	15/60

Dated: July 26, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–19324 Filed 7–31–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers, Supplemental Awards under Program Announcement 98047

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting. This notice is published less than 15 days in advance of the meeting due to administrative delays.

NAME: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers, Supplemental Awards under Program Announcement 98047, meeting.

TIMES AND DATES: 1 p.m.–1:30 p.m., August 9, 2000 (Open). 1:30 p.m.–4 p.m., August 9, 2000 (Closed).

PLACE: The teleconference call will originate in the National Center for Chronic Disease Prevention and Health Promotion, Prevention Research Centers Program, Koger Center, Rhodes Building, 3005 Chamblee Tucker Rd., Atlanta, Ga 30341. Open access to the call will be available from 1–1:30 p.m. EDT, only. Interested parties may access the teleconference at 877/331–6867. The participant code is 949464.

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 Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

MATTERS TO BE DISCUSSED: The meeting will include the review, discussion, and evaluation of supplemental award applications received in response to Program Announcement 98047.

CONTACT PERSON FOR MORE INFORMATION: David Elswick, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway m/s K30, Atlanta, GA., 30341. Telephone 770/488–5395, email dce1@cdc.gov.

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: July 25, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–19462 Filed 7–28–00; 10:36 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1418]

International Conference on Harmonisation; Draft Guidance on Good Manufacturing Practice for Active Pharmaceutical Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document is intended to provide guidance regarding current good manufacturing practice (CGMP) for manufacturing of active pharmaceutical ingredients (API's). The recommendations in the draft guidance are intended to assist in the manufacture of API's that meet the standards for quality and purity they purport or are represented to possess.

DATES: Submit written comments by October 2, 2000.

ADDRESSES: Copies of the draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests.

To facilitate the submission and review of comments on this draft guidance, the agency has developed two methods for submitting electronic comments. Interested persons may submit comments to the Dockets Management Branch (HFA–305) online or offline by downloading a comments template. Both methods are accessible on the FDA web site at http://www.fda.gov/ohrms/dockets. The agency encourages the submission of electronic comments and anticipates that widespread use of these methods

will increase the effectiveness of the guidance development process.

Interested parties may also submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:*

Joseph X. Phillips, Central Regional Office, U.S. Customhouse, 2d and Chestnut Sts., rm. 900, Philadelphia, PA 19106, 215–597–0492, JPhillip@ora.fda.gov, or

Edwin Rivera, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0095, Rivera@cder.fda.gov, or

John A. Eltermann, Center for Biologics Evaluation and Research (HFM–670), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031, Eltermann@cber.fda.gov.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: 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, the Canadian Health Protection Branch, and the European Free Trade Area.

In July 2000, the ICH Steering Committee agreed that a draft guidance entitled ''Q7A ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

In accordance with FDA's good guidance practices (GGP's) (62 FR 8961, February 27, 1997), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency is changing its procedure for publishing ICH guidances. Beginning April 2000, we will no longer include the text of ICH guidances in the **Federal Register**. Instead, we will publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). The draft guidance will be left in the original ICH format. The final guidance will be reformatted to conform to the GGP style before publication.

The draft guidance describes CGMP for the manufacturing of API's. The recommendations in the draft guidance are intended to assist in the manufacture of API's that meet the standards for quality and purity they purport or are represented to possess. The draft guidance is not intended to define registration or filing requirements or modify pharmacopeial requirements.

In the draft guidance, ''manufacturing'' includes all operations, and related controls, of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage, and distribution of API's. The draft guidance applies to the manufacture of API's for use in human drug products, including sterile API's up to the point immediately before the API is rendered sterile. The sterilization and aseptic processing of sterile API's are not covered by this draft guidance. CGMP's described in the draft guidance should be applied to the API manufacturing process beginning with the use of starting materials.

The draft guidance applies to API's that are manufactured by chemical synthesis, extraction, cell culture/fermentation, recovery from natural sources, or any combination of these processes. Intermediates and API's produced by recombinant DNA technology are covered provided they are proteinacious materials.

The draft guidance does not apply to vaccines, whole cells, whole blood and plasma, and API's derived from plasma fractionation, but does apply to API's produced using blood or plasma as raw materials. The draft guidance does not apply to cell substrates, medical gases, bulk-packaged drug products, and manufacturing/control aspects specific to radiopharmaceuticals.

This draft guidance represents the agency's current thinking on CGMP's for manufacturing of API's. 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, regulations, or both.

Interested persons may submit electronic comments to the Dockets Management Branch (http://www.fda.gov/ohrms/dockets) by October 2, 2000. Written comments also can be submitted on the draft guidance (address above). Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19332 Filed 7–27–00; 1:45 pm]

BILLING CODE 4160–01–F