158–15 Liberty Ave., Jamaica, NY 11433, 718–662–5416; or H. Gregg Claycamp, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–4354.

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, Labour, 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.

During the July 2003 ICH meeting in Brussels, agreement was reached on a common vision and approach for developing an international plan for a harmonized pharmaceutical quality system that would be applicable across the lifecycle of a product. This plan emphasizes an integrated approach to review (assessment) and inspection based on scientific risk management. One aspect of the plan was the establishment of an expert working group to develop guidance for quality risk management.

In March 2005, the ICH Steering Committee agreed that a draft guidance entitled ''Q9 Quality Risk Management'' should be made available for public comment. The draft guidance is the product of the Quality Risk Management Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the ICH expert working group.

The draft guidance provides principles and examples of tools for quality risk management that can be applied to all aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. These quality risk management approaches apply to the development, manufacturing, distribution, inspection, and submission/review processes, including the use of raw materials, solvents, excipients, and packaging and labeling materials. The draft guidance is intended to support other ICH quality documents, to complement existing quality practices and standards, and to enable regulators and industry to make more effective and consistent risk-based decisions.

This document supports FDA's ''Pharmaceutical Current Good Manufacturing Practices for the 21st Century'' initiative, which was intended to bring a 21st century focus to the regulation of pharmaceutical manufacturing and product quality. One objective of this initiative is to encourage the implementation of risk-based approaches that focus both industry and agency attention on critical areas.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on Q9 quality risk management. 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/reading.htm*.

Dated: August 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–15546 Filed 8–5–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, (Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques of other forms of information technology.

Proposed Project: The Sentinel Centers Network (SCN) Core Data Set (OMB No. 0915–0268)—Extension.

HRSA's Bureau of Primary Health Care (BPHC) established the Sentinel Centers Network (SCN) to assist in addressing critical policy issues. Health centers identified as having adequate infrastructure and commitment through the competitive contract process have generated data for quality and program analyses and for projects on topics that have immediate programmatic impact. Health centers submit core data periodically extracted from existing information systems. These core data comprise patient, encounter, and practitioner level information including patient demographics, insurance status, clinical diagnoses and procedures, outcomes, and practitioner characteristics. Since all data obtained from the participant health centers is extracted/compiled from existing information systems, and not through primary data collection, burden is minimized. In addition, each participant site receives technical assistance as needed to reduce burden and facilitate data submission.

The annual burden estimate for this activity is as follows:

Type of respondent	Number of responses	Responses per respondents	Total responses	Hours per response	Total burden hours
Sites	43	2	86	8	688

Send comments to Susan G. Queen, PhD., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received with 60 days of this notice.

Dated: August 1, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–15612 Filed 8–5–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: September 13, 2005, 8:30 a.m.—5 p.m.; and September 14, 2005, 8:30 a.m.—12:15 p.m.

Place: Holiday Inn Select, Washington Room (2nd Floor), 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Agenda: The agenda for September 13 in the morning will include: Welcome and opening comments from the Executive Secretary of COGME and management staff of the Health Resources and Services Administration. Following will be an election of the Chair of COGME. Later that morning there will be a discussion on processes for producing the next COGME report. In the afternoon there will be a discussion of potential report topics.

The agenda for September 14 will include a continued discussion of potential report topics and resolution of the next report topic.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Anyone requiring information regarding the meeting should contact Jerald M. Katzoff, Deputy Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6785.

Dated: August 1, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–15611 Filed 8–5–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Acting Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset