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's Health Products and Food Branch, and the European Free Trade Area.

In the **Federal Register** of June 14, 2002 (67 FR 40949), FDA published a draft tripartite guidance entitled ''Evaluation of Stability Data.'' The notice gave interested persons an opportunity to submit comments by August 1, 2002.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in February 2003.

This guidance complements an ICH guidance entitled ''Q1A(R2) Stability Testing of New Drug Substances and Products,'' which was revised from Q1A(R) and published in the **Federal Register** of November 21, 2003. The guidance is intended to provide recommendations on how to use stability data, generated in accordance with the principles outlined in Q1A(R2), to propose a retest period for the drug substance and a shelf life for the drug product.

The recommendations on the evaluation and statistical analysis of stability data provided in Q1A(R2) are brief in nature and limited in scope. Although Q1A(R2) states that regression analysis is an acceptable approach to analyzing quantitative stability data for retest period or shelf life estimation and recommends that a statistical test for batch poolability be performed using a level of significance of 0.25, it includes few details. In addition, Q1A(R2) does not cover situations where multiple factors are involved in a full- or reduced-design study. This guidance provides a clear explanation of the expectations when proposing a retest period or shelf life and storage conditions based on the evaluation of stability data for both quantitative and qualitative test attributes. It outlines recommendations for establishing a retest period or shelf life based on stability data from single or multifactor and full- or reduced-design studies. The guidance further describes when and how limited extrapolation can be undertaken to propose a retest period or shelf life beyond the observed range of data from the long-term storage condition.

This guidance represents 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 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 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: May 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12889 Filed 6–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Revision

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current record keeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.

ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b)(2) OPTN membership and application requirements for OPOs, hospitals, and histocompatibility laboratories	30	1	30	40	1,200

ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN—Continued

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.6(c) (Reporting) Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure) Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4) Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(e) Transplant to prevent organ wastage	278	1.5	417	0.5	209
121.9(b) Designated Transplant Program Requirements	10	1	10	5.0	50
Total	944		36,457		19,459

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 1, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–12890 Filed 6–7–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; 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: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: July 13, 2004, 9 a.m.–5 p.m. July 14, 2004, 8:30 a.m.–3 p.m.

Place: The Hotel Washington, 15th & Pennsylvania Avenue, NW., Washington, DC 20004, (202) 638–5900.

Status: The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start initiative and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Low Birth Weight, Preterm Birth, U.S. and International Infant Mortality Data, the Healthy Start Program and Evaluation. Agenda items are subject to change as priorities are further determined.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr.P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–6327.

Dated: June 1, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–12891 Filed 6–7–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Draft Supplemental Compliance Program Guidance for Hospitals

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on a draft supplemental compliance program guidance (CPG) for hospitals developed by the Office of Inspector General (OIG). When the final version of this document is published, it will supplement the OIG's prior compliance program guidance for hospitals issued in 1998. This draft contains new compliance recommendations and an expanded discussion of risk areas. The draft takes into account recent changes to hospital payment systems and regulations, evolving industry practices, current enforcement priorities, and lessons learned in the area of corporate compliance. When published, the final supplemental CPG will provide voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on July 23, 2004.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–9–CPG, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–9–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 2 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton or Paul Johnson, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Background

Several years ago, the OIG embarked on a major initiative to engage the private health care community in preventing the submission of erroneous claims and in combating fraud and abuse in the Federal health care programs through voluntary compliance efforts. In the last several years, the OIG has developed a series of compliance program guidances (CPGs) directed at the following segments of the health care industry: Hospitals; clinical