

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0528]

International Conference on Harmonisation; Guidance on E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The questions and answers (Q&A) guidance addresses special considerations for the design and conduct of clinical trials of drugs likely to have significant use in the elderly. The Q&As are intended to provide guidance on the use of geriatric data to adequately characterize and represent the safety and efficacy of a drug for a marketing application, including data collected postmarketing.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance:

Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4212, Silver Spring, MD 20993-0002 301-796-2270; or

Nisha Jain, Center for Biologics Evaluation and Research (HFM-392), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6110.

Regarding the ICH:

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3506, Silver Spring, MD 20993-0002, 301-796-4600.

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.

In the **Federal Register** of November 10, 2009 (74 FR 58024), FDA published a notice announcing the availability of a draft guidance entitled "E7 Studies in Support of Special Populations: Geriatrics Questions & Answers." The notice gave interested persons an opportunity to submit comments by January 11, 2010.

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 July 2010.

The Q&A guidance addresses special considerations for the design and conduct of clinical trials of drugs that are likely to have significant use in the elderly. The Q&As are intended to provide guidance on the use of geriatric data to adequately characterize and represent the safety and efficacy of a drug for a marketing application, including data collected postmarketing.

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 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: February 14, 2012.

Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2012-3955 Filed 2-17-12; 8:45 am]
BILLING CODE 4160-01-P

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)(A) 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) publishes 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 and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions

of the Agency; (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 or other forms of information technology.

Proposed Project: Rural Health Information Technology Network Development (OMB No. 0915-xxxx) – [New]

The purpose of the Rural Health Information Technology Network Development (RHITND) Program, authorized under the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c) as amended by Section 201, Public Law 107-251 of the Health Care Safety Net Amendments of 2002, is to improve health care and support the adoption of Health Information Technology (HIT) in rural America by providing targeted HIT support to rural health networks. HIT plays a significant role in the advancement of the Department of Health and Human Services' (HHS) priority policies to improve health care delivery. Some of these priorities include: improving health care quality, safety, and efficiency, reducing disparities, engaging both patients and families in managing their health, enhancing care coordination, improving population and

public health, and ensuring adequate privacy and security of health information.

The intent of RHITND is to support the adoption and use of electronic health records (EHR) in coordination with the ongoing HHS activities related to the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111-5). This legislation provides HHS with the authority to establish programs to improve health care quality, safety, and efficiency through the promotion of health information technology, including EHR.

For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy (ORHP), including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health-related clinical measures. Several measures will be used for this program. These measures will speak to ORHP's progress toward meeting the goals set.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Rural Health Information Technology Network Development Program	41	1	41	4.12	168.92
Total	41	1	41	4.12	168.92

Email comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 14, 2012.

Reva Harris,
Acting Director, Division of Policy and Information Coordination.
 [FR Doc. 2012-3919 Filed 2-17-12; 8:45 am]
BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2011-1074]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.
ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs

(OIRA), requesting approval of a revision to the following collection of information: 1625-0010, Defect/Noncompliance Report and Campaign Update Report. Our ICRs describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before March 22, 2012.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2011-1074 to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid