

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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[Docket No. FDA-2008-D-0199] (formerly Docket No. 2006D-0526)

**International Conference on Harmonisation; Guidance on E15  
Pharmacogenomics Definitions and Sample Coding; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories.” 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 guidance contains definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. In the effort to develop harmonized approaches to drug regulation, it is important to ensure that consistent definitions of terminology are being applied across all constituents of the ICH. The guidance is intended to facilitate the integration of the discipline of pharmacogenomics and pharmacogenetics into global drug development and approval processes.

**DATES:** Submit written or electronic comments on agency guidance at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), 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, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

*Regarding the guidance:* Felix Frueh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4512, Silver Spring, MD 20993-0002, 301-796-1530; or Raj K. Puri, Center for Biologics Evaluation and Research (HFM-735), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0471.

*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**

FDA is announcing the availability of a guidance entitled “E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories.” 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 January 8, 2007 (72 FR 793), FDA published a notice announcing the availability of a draft guidance entitled "E15

Terminology in Pharmacogenomics.” The notice gave interested persons an opportunity to submit comments by April 9, 2007.

After consideration of the comments received and revisions to the guidance, a final version of the draft guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in October 25, 2006.

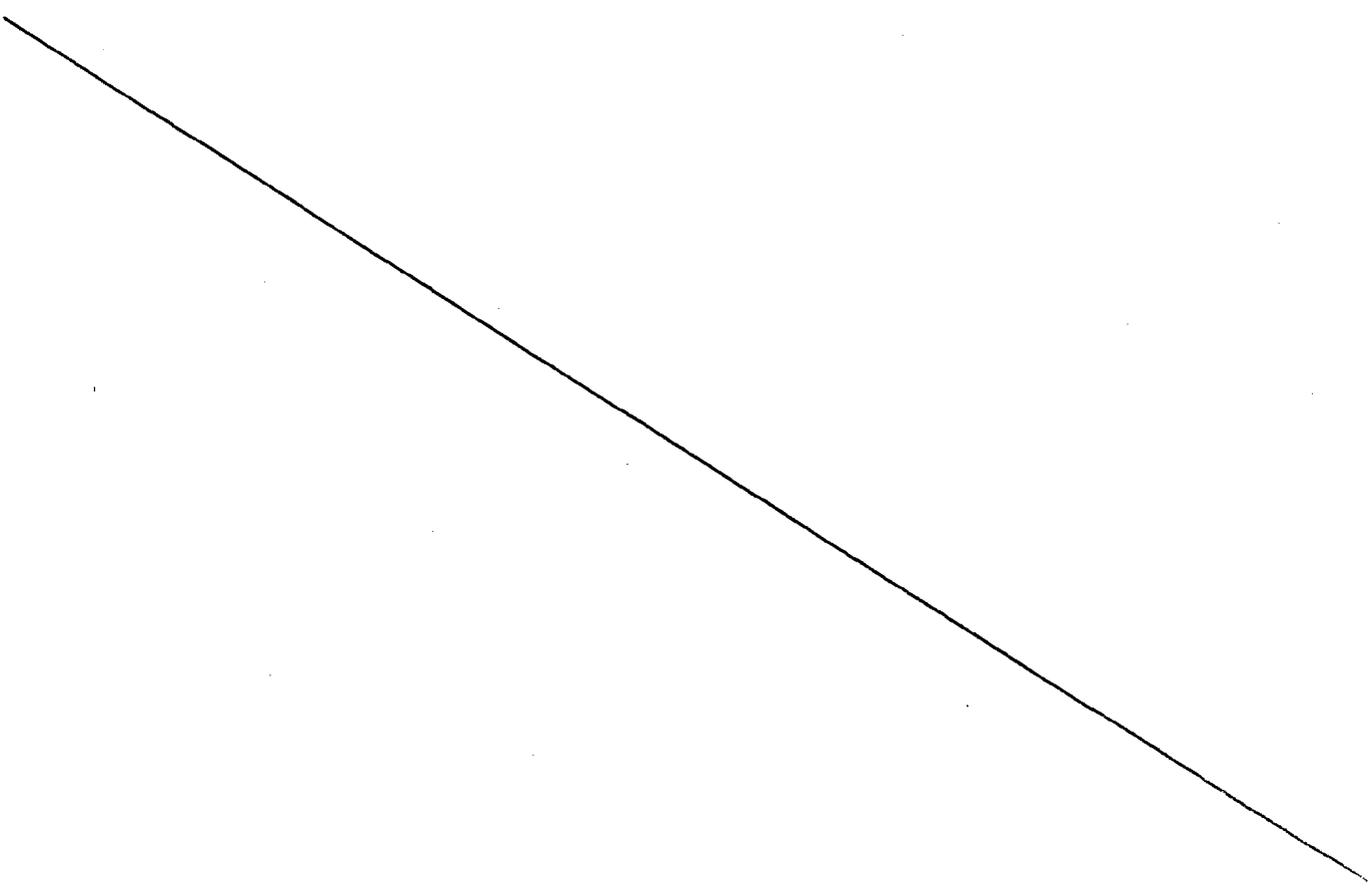
The guidance represents an international effort to harmonize pharmacogenomics definitions and sample coding. Inconsistent definitions make it difficult to achieve agreement on parameters for implementation of pharmacogenomics in global pharmaceutical development, and might lead to inconsistent assessments by regulators. The guidance provides definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. The guidance is intended to facilitate the integration of the discipline of pharmacogenomics and pharmacogenetics into global drug development and approval processes. Timely harmonization of terminology and definitions will create a common foundation for future guidance on pharmacogenomics.

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**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.



**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: 3 / 28 / 08  
March 28, 2008.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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Sydney Reese