

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0497]

Guidance for Industry on Pharmacogenomic Data Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Pharmacogenomic Data Submissions.” The guidance provides recommendations to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decisionmaking. The guidance is intended to facilitate scientific progress in the area of pharmacogenomics.

DATES: Submit written or electronic comments on agency guidance documents 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, 5600 Fishers Lane, Rockville, MD 20857 or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Lawrence Lesko, Center for Drug Evaluation and Research (HFD–850),
Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,
301–594–5690, or

Raj Puri, Center for Biologics Evaluation and Research (HFM–735), Food
and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–
1448, 301–827–0471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Pharmacogenomic Data Submissions.” Although the field of pharmacogenomics is in its infancy, the promise of pharmacogenomics lies in its potential to predict sources of interindividual variability in drug response (both efficacy and toxicity), thus allowing individualization of therapy to maximize effectiveness and minimize risk. Pharmaceutical sponsors have been reluctant to embark on programs of pharmacogenomic testing during the FDA-regulated phases of drug development, due to uncertainties in how FDA will react to the data being generated. This guidance is intended to facilitate scientific progress in the area of pharmacogenomics.

The guidance is one of several efforts under way to facilitate pharmacogenomic testing. FDA will make available soon a concept paper entitled “Concept Paper on Pharmacogenomic Drug Diagnostic Co-

Development.” The concept paper is the first step in development of a draft guidance on that topic.

On November 4, 2003 (68 FR 62461), FDA announced a document announcing the availability of the draft version of this guidance. A number of comments were received. The agency considered them carefully as it finalized the guidance and made appropriate changes. For the most part, the changes clarified statements made in the draft version. The following changes are noteworthy: (1) Appendix D (examples of pharmacogenomic data submissions) is no longer part of the guidance and has been moved into a separate document that will be available with the final guidance so that additional examples can be added over time; (2) a new appendix E has been added, a voluntary submission cover sheet, which should be used when submitting a “voluntary” genomic data submission to clearly distinguish such a submission from regular IND, NDA, or BLA submissions; (3) two fundamental issues regarding the procedure of submitting and reviewing voluntary genomic data submissions and the function and responsibilities of the Interdisciplinary Pharmacogenomics Review Group were addressed by creating separate internal agency procedures (i.e., the Center for Drug Evaluation and Research Manual of Policy and Procedures or the Center for Biologics Evaluation and Research Manual of Standard Operating Procedures and Policies) rather than including the information in the guidance document.

II. The Paperwork Reduction Act of 1995

In the **Federal Register** of November 4, 2003 (68 FR 62461), FDA published a 60-day notice requesting public comment on the information collection provisions of this guidance. In the **Federal Register** of August 11, 2004 (69 FR 48876), the agency announced that it was submitting the collection of

information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910–0557. This approval expires December 31, 2007. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This level 1 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 statute, regulations, or both.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed 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 guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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