

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0012]

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Certifier L. CLAWSON
DDM

**Guidance for Industry and Food and Drug Administration Staff;
Pharmacogenetic Tests and Genetic Tests for Heritable Markers; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled “Pharmacogenetic Tests and Genetic Tests for Heritable Markers.” This document is intended to provide guidance on preparing and reviewing premarket approval applications (PMAs) and 510(k) submissions for pharmacogenetic and other genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Pharmacogenetic Tests and Genetic Tests for Heritable Markers” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. You may also obtain the guidance by mail by calling the Center for Biologics Evaluation and Research at 1-800-835-4709

or 301–827–1800, or by faxing your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert Becker, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0493, ext. 212.

For use of the guidance in relation to applications to CBER contact: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

For use of the guidance in relation to applications to CDER contact: Felix Frueh, Office of Clinical Pharmacology and Biopharmaceutics (HFD–850), 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–1530.

SUPPLEMENTARY INFORMATION:

I. Background

The draft of this guidance document was published in the **Federal Register** of February 9, 2006 (71 FR 6779). The guidance provides recommendations on preparing and reviewing PMAs and 510(k) submissions for pharmacogenetic and other human genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests). FDA received several sets

of comments on the guidance and considered all comments. The guidance was revised where needed to provide additional clarification.

II. Significance of Guidance

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 pharmacogenetic tests and genetic tests for heritable markers. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Pharmacogenetic Tests and Genetic Tests for Heritable Markers" you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1594 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. Search capabilities for guidance documents are available at <http://www.fda.gov/cdrh/guidance.html> (for CDRH guidances) and

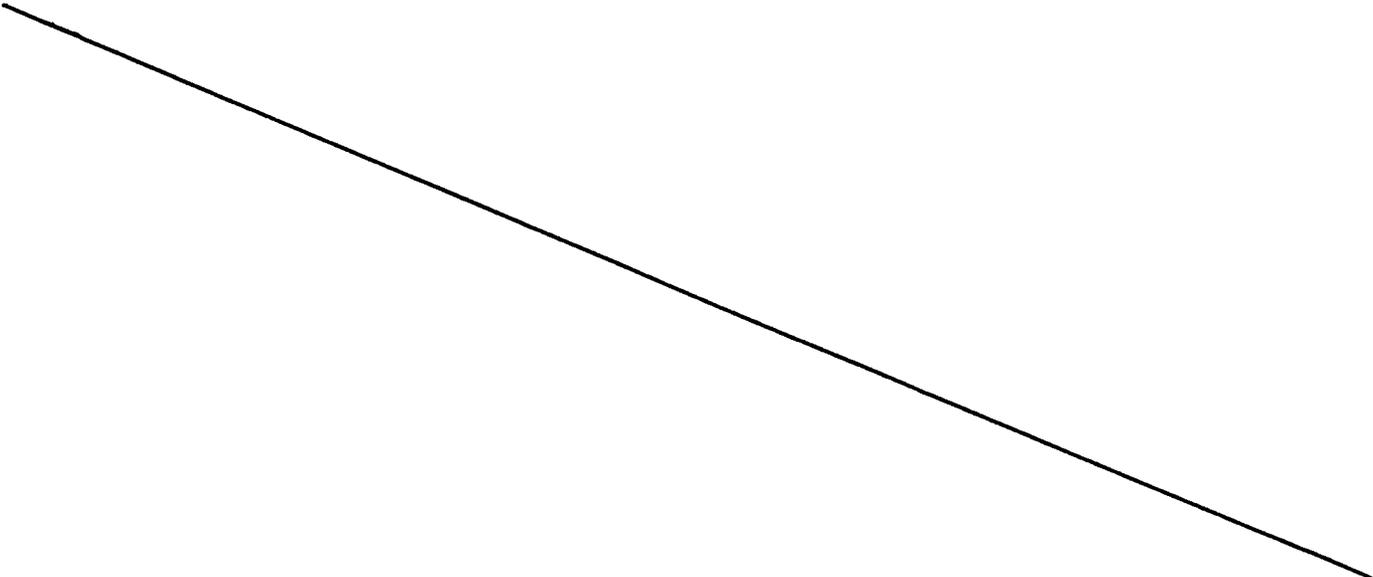
<http://www.fda.gov/cber/guidelines.htm> (for CBER guidances). Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

V. Comments

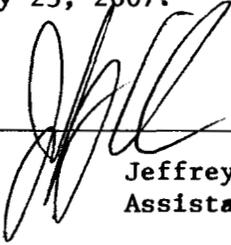
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be 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.

Dated: 5/23/07

May 23, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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COPY OF THE ORIGINAL**

