

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006D-0012]

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Display Date	2-8-06
Production Date	2-9-06
Control	J. Coone

**Draft Guidance for Industry and Food and Drug Administration Staff;  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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Pharmacogenetic Tests and Genetic Tests for Heritable Markers." This draft guidance document is intended to provide guidance on preparing and reviewing premarket approval applications (PMAs) and 510(k) submissions for pharmacogenetic and other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**DATES:** Submit written or electronic comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Pharmacogenetic Tests and Genetic Tests for Heritable Markers" to the Division of Small Manufacturers, International, and Consumer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 or submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration,

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1401 Rockville Pike, 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. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 (CDRH) (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 the Center for Drug Evaluation and Research (CDER), contact:* Allen Rudman, Office of Clinical Pharmacology and Biopharmaceutics (HFD–850), Food and Drug Administration, 10903 New Hampshire Ave., W021, rm. 3666, Silver Spring, MD 20993–0002, 301–796–1597.

**SUPPLEMENTARY INFORMATION:**

## I. Background

This draft guidance document 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). Tests of gene expression and tests for non-heritable (somatic) mutations are not specifically addressed, although many of the same principles may apply. Likewise, this draft guidance specifically addresses only nucleic-acid based analysis, but some of the principles may be applied to other matrices (e.g., protein), when the purpose is to provide genetic information.

FDA issued an earlier version of this draft guidance on February 27, 2003, entitled “Draft Guidance for Industry and FDA Reviewers; Multiplex Tests for Heritable DNA Markers, Mutations and Expression Patterns.” The notice of availability for the February 27, 2003, draft guidance was published in the **Federal Register** of April 21, 2003 (68 FR 19549) and the comment period closed on July 21, 2003. As explained in the February 27, 2003, draft guidance and April 21, 2003, document, we recognized that discussions on this topic had been introductory. Because of this, we explained that the February 2003 draft guidance would be followed by another draft guidance that would provide an opportunity for additional discussion. As stated in the April 2003 document, we believe the public health will benefit from this dialogue with industry about appropriate ways to review this technology.

We received several comments on the 2003 draft guidance, which included comments suggesting that the draft guidance was too broad in scope. The 2003 draft guidance document addressed both gene expression and genetic tests. The draft guidance announced in this **Federal Register** document,

“Pharmacogenetic Tests and Genetic Tests for Heritable Markers,” instead focuses on genetic tests.

In developing the draft guidance announced in this document, FDA considered the comments received on the 2003 draft guidance and also information we received through our participation at seminars and workshops with representatives from the drug and device industries, professional societies, laboratory professionals, healthcare providers, and other stakeholders. These seminars and workshops included discussions of the criteria that are important in the analytical and clinical validation of multiplex tests, including pharmacogenetic and genetic assays. These discussions also explored the kind of information the industry might submit to the agency to achieve the least burdensome means of demonstrating substantial equivalence or evaluating safety and effectiveness.

## **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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**

To receive “Pharmacogenetic Tests and Genetic Tests for Heritable Markers” by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the

document number (1549) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

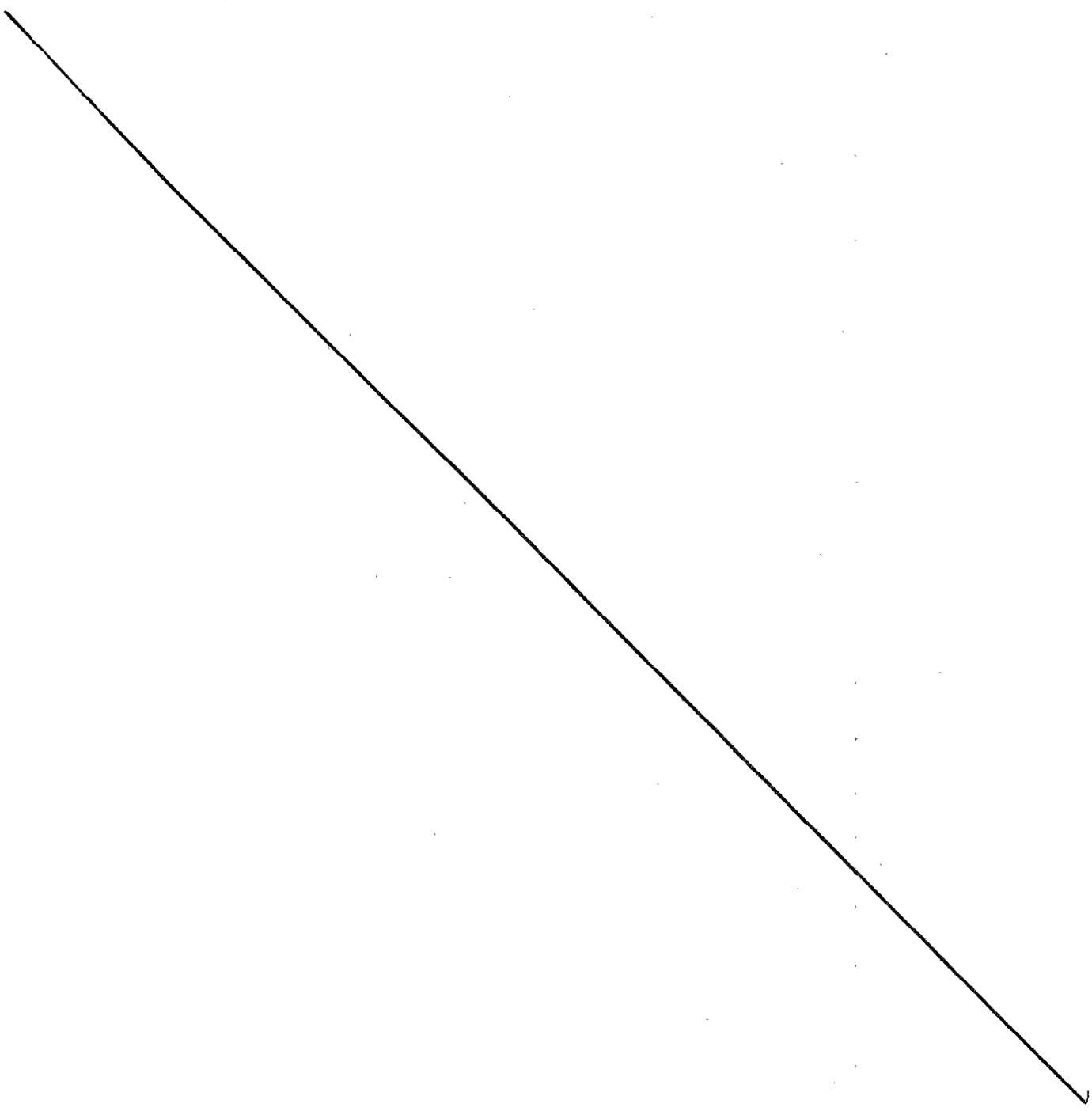
Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, 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>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. CBER's guidance documents are available at <http://www.fda.gov/cber/guidelines.htm>. 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 draft 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 No. 0910–0120; 21 CFR part 814 have been approved under OMB Control No. 0910–0231; 21 CFR part 801 and 21 CFR part 809 have been approved under OMB Control No. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/1/06  
February 1, 2006.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Linda S. Kahan

Linda S. Kahan,  
Deputy Director,  
Center for Devices and Radiological Health.  
[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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**BILLING CODE 4160-01-S**