

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0195]

Science Board to the Food and Drug Administration; Amendment of Notice; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of June 7, 2007 (72 FR 31587). The document announced an amendment to the notice of meeting of the Science Board to the Food and Drug Administration. The meeting was originally announced in the **Federal Register** of May 21, 2007 (72 FR 28499). The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 07-2829, appearing on page 31587 in the **Federal Register** of Thursday, June 7, 2007, the following correction is made:

1. On page 31587, in the first column, in the heading of the document, “[Docket No. 2007N-0208]” is corrected to read “[Docket No. 2007N-0195]”.

Dated: June 11, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-11727 Filed 6-18-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0012]

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: May 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11817 Filed 6–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5117–N–48]

Notice of Submission of Proposed Information Collection to OMB; Restriction on Assistance to Noncitizens

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

Section 214 of the Housing and Community Development Act of 1980, as amended, prohibits HUD from making financial assistance available for noncitizens, unless they meet one of the categories of eligible immigration status specified in Section 214. Prior to being admitted, all eligible noncitizens younger than age 62 must sign a declaration of their status and a verification consent form and provide their original Immigration and Naturalization Service (INS) documentation.

DATES: *Comments Due Date:* July 19, 2007.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2501–0014) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Lillian_L_Deitzer@HUD.gov or telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Deitzer or from HUD’s Web site at <http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm>.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information

collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Restriction on Assistance to Noncitizens.

OMB Approval Number: 2501–0014

Form Numbers: HUD–9886, HUD–9887.

Description of the Need for the Information and Its Proposed Use: Section 214 of the Housing and Community Development Act of 1980, as amended, prohibits HUD from making financial assistance available for noncitizens, unless they meet one of the categories of eligible immigration status specified in Section 214. Prior to being admitted, all eligible noncitizens younger than age 62 must sign a declaration of their status and a verification consent form and provide their original Immigration and Naturalization Service (INS) documentation.

Frequency of Submission: On occasion, Annually.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	2,886,392	3.74		.0333		360,214