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 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: Maria M. Chan, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0493, ext. 130.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying automated FISH enumeration systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for automated FISH enumeration systems.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving written notice classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device.

Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on automated FISH enumeration systems. 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 ''Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems'' 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 (1550) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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 cleared submissions, 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*. 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 contains information collection provisions that 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 premarket notification submission provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0120. The labeling provisions addressed in the guidance have been approved by OMB 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: March 10, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–5642 Filed 3–22–05; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. 05–5381 Filed 3–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Office of AIDS Research Advisory Council.

Date: April 7, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: A Report of the Director addressing OAR initiatives. The meeting will focus on the burden of HIV disease on women.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 6C10, Bethesda, MD 20892.

Contact Person: Jack Whitescarver, Director, Office of AIDS Research, OD, National Institutes of Health, 9000 Rockville Pike, Building 2, Room 4E14, Bethesda, MD 20892, (301) 496–0357.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-