using an asset-based approach for assisting individuals and families with low incomes out of poverty. The program supports grantee organizations that provide financial literacy education and other training to families, along with access to IDAs. Every dollar in savings deposited into an IDA by a participant will be matched with AFI grant funds and non-federal funds. The program promotes savings and enables participants to acquire an economic asset that will appreciate over the long-term. Participants use their IDA savings to acquire a first home, capitalize a small business, or enroll in postsecondary education or training.

The Native Asset Building Initiative is designed to create synergies between the SEDS program and the AFI program, and to provide enhanced funding opportunities for Native communities. OCS and ANA anticipate that the Native Asset Building Initiative funding opportunity announcement will be published in April 2011. Upon publication, the Native Asset Building Initiative funding opportunity announcement will be made available at *http://www.Grants.gov* and at ACF Funding Opportunities *http://www.acf.hhs.gov/grants/index.html*.

Information on the planned announcement may now be accessed at the HHS Grants Forecast Web site at *http://www.acf.hhs.gov/hhsgrantsforecast/*.

OCS will publish a synopsis of comments received as a result of this notice, along with the agency's responses.

DATES: The deadline for receipt of comments is 30 days from the date of publication of this notice in the **Federal Register**.

ADDRESSES: Comments in response to this notice should be addressed to James Gatz, Manager, Assets for Independence Program, Office of Community Services, 370 L'Enfant Promenade, SW., Mailstop Aerospace 5–West, Washington, DC 20447. Comments will be available for inspection by members of the public at the Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Jennifer Medina, Program Specialist, (866) 778–6037.

Dated: March 23, 2011.

Yolanda Butler,

Acting Director, Office of Community Services.

[FR Doc. 2011–7649 Filed 3–31–11; 8:45 am]

BILLING CODE 4184–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0283]

Guidance for Industry on Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act; 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 "Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing FDA to require certain postmarketing studies and clinical trials for prescription drugs approved under the FD&C Act and biological products approved under the Public Health Service Act (the PHS Act). This guidance provides information on the implementation of the new provisions and a description of the types of postmarketing studies and clinical trials that will generally be required under the new legislation (postmarketing requirements (PMRs)) and the types that will generally be agreed-upon commitments (postmarketing commitments (PMCs)) because they do not meet the new statutory criteria for required postmarketing studies and clinical trials.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. 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 the office in processing your requests.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Nancy Dickinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6226, Silver Spring, MD 20993–0002, 301–796–5400; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act." In the past, FDA has used the term "PMC" to refer to studies (including clinical trials), conducted by an applicant after FDA has approved a drug for marketing or licensing, that were intended to further refine the safety, efficacy, or optimal use of a product, or to ensure consistency and reliability of product quality. These commitments were either agreed upon by FDA and the applicant or, in certain circumstances, required by FDA. Prior to the passage of FDAAA, FDA required PMCs in the following situations:

- Subpart H and subpart E accelerated approvals, which require postmarketing studies to demonstrate clinical benefit (21 CFR 314.510 and 601.41);
- Deferred pediatric studies, where studies are required under the Pediatric Research Equity Act (section 505, FD&C Act); and
- Animal Efficacy Rule approvals, where studies to demonstrate safety and efficacy in humans are required at the time of use (21 CFR 314.610(b)(1) and 601.91(b)(1)).

Title IX, section 901 of FDAAA (Pub. L. 110–85) amended the FD&C Act by adding new section 505(o) (21 U.S.C. 355(o)). Section 505(o)(3) of the FD&C Act authorizes FDA to require certain postmarketing studies or clinical trials for prescription drugs approved under section 505(b) of the FD&C Act and biological products approved under section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(3)(B) of the FD&C Act states that postmarketing studies and clinical trials may be required for one of three purposes:

- To assess a known serious risk related to the use of the drug;

• To assess signals of serious risk related to the use of the drug; or

• To identify an unexpected serious risk when available data indicates the potential for a serious risk.

This guidance provides information on the implementation of new section 505(o)(3) of the FD&C Act. The guidance also describes which types of postmarketing studies and clinical trials will be required (PMRs) under section 505(o)(3) and which types will be agreed-upon commitments because they do not meet the statutory criteria for required studies and trials (PMCs).

In the **Federal Register** of July 15, 2009 (74 FR 34358), FDA announced the availability of a draft guidance for industry entitled "Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act." The notice gave interested persons the opportunity to comment by October 13, 2009. The draft guidance was revised in response to comments submitted to the docket requesting that the guidance clearly distinguish PMRs required under section 505(o)(3) of the FD&C Act from risk evaluation and mitigation strategies. The revisions also provide additional detail in the examples of PMRs and PMCs and clarify reporting requirements.

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 the implementation of section 901 of FDAAA on postmarketing studies and clinical trials. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

III. Paperwork Reduction Act of 1995

This guidance provides information on the implementation of section 901 of FDAAA. The collections of information requested in the draft guidance would be submitted under 21 CFR 314.80, 314.81, and 601.70. 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) and are approved under OMB control numbers 0910–0230, 0910–0001, and 0910–0338. Section VI of the guidance refers to procedures in the guidance entitled "Formal Dispute Resolution: Appeals Above the Division Level," which contains collections of information approved under OMB control number 0910–0430.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: March 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–7707 Filed 3–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0066]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until May 2, 2011, the comment period for the notice announcing a meeting of the Molecular and Clinical Genetics Panel (the panel) of the Medical Devices Advisory Committee that published in the **Federal Register** of February 7, 2011 (76 FR 6623). In the notice, FDA requested public comment regarding the March 8 and 9, 2011, meeting of the panel to discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims. FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments and information by May 2, 2011.

ADDRESSES: Submit electronic comments or information to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 7, 2011 (76 FR 6623), FDA published a notice announcing a meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee, and the opening of a public docket to seek input and comments from interested stakeholders to discuss scientific issues concerning DTC tests. Interested persons were given until March 1, 2011, to submit comments.

II. Request for Comments

Following publication of the February 7, 2011, notice, FDA received requests to allow interested persons additional time to comment. The requesters asserted that the initial time period was insufficient to allow potential respondents to thoroughly evaluate and assess pertinent issues. The Agency has considered the requests and is reopening the comment period until May 2, 2011.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding the meeting. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–7708 Filed 3–31–11; 8:45 am]

BILLING CODE 4160–01–P