

lawyers as specialist is child welfare, develops and implements child representation research and demonstration projects to promote evidence-based, evidence-informed practice improvements and effective child representation, establishes and maintains a national information sharing network to disseminate information on promising practices; evaluates the impact of selected projects implementing the child representation models on outcomes for children and families who have competent and effective child representation, and identifies barriers and recommends need changes in laws, policies, procedures and/or practice. The supplemental funds will be used to provide additional training, technical assistance, and support to each research and demonstration site to fully implement and maintain rigorous on-site and cross-site evaluation plans.

FOR FURTHER INFORMATION CONTACT: Gail Collins, Children's Bureau, 1250 Maryland Avenue, SW., Washington, DC 20047. Telephone: 202-205-8552, e-mail: gail.collins@acf.hhs.gov.

Dated: March 23, 2011.

Bryan Samuels,

Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Request for Public Comment on Proposed Funding Opportunity Announcement for Special Initiative Concerning the Assets for Independence Program

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Request for Public Comment.

C.F.D.A. Number: 93.602

Statutory Authority: The Assets for Independence Act (Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, as amended, Pub. L. 105-285, 42 U.S.C. 604 note) authorizes the Department of Health and Human Services to award grants to support Assets for Independence (AFI) projects and to research and evaluate the effectiveness of the AFI program and Individual Development Accounts (IDAs).

SUMMARY: In FY 2011, the Office of Community Services (OCS) will coordinate with the Administration on Native Americans (ANA) to implement

the Native Asset Building Initiative, through which the two offices will support Tribes and Native organizations in planning and implementing comprehensive asset-building projects. The initiative will feature special grants through the Assets for Independence (AFI) program. These grants will be in addition to the annual AFI grants that OCS will award in FY 2011. In contrast to the annual awards, though, the eligibility criteria to be listed for these AFI grants in the "Native Asset Building Initiative" will vary from the annual AFI awards' eligibility criteria. This is because the criteria used to determine eligibility for these special initiative awards will be more consistent with those used to determine eligibility in the ANA grant program with which OCS is coordinating. Consequently, the eligibility for the special AFI grants will be limited to Native 501(c)(3) non-profits serving Native Americans; Federally recognized Tribal governments or Alaska Native Villages, as defined in the Alaska Native Claims Settlement Act, that are joint applicants with a 501(c)(3) Native non-profit organization; and Native non-profit organizations designated by the Secretary of the Treasury as Community Development Financial Institutions and Native non-profit credit unions designated by the National Credit Union Administration as low-income credit unions that demonstrate a collaborative relationship with a local community based organization whose activities are designed to address poverty and the needs of community members for economic independence and stability. Other entities will not be eligible for awards under this initiative, but will continue to be eligible for awards under the annual AFI funding opportunity announcement that was published issued for FY 2011 through FY 2013 on February 24, 2011 on <http://www.acf.hhs.gov/grants/open/foa/view/HHS-2011-ACF-OCS-EI-0137>.

It is estimated that OCS will award up to 10 AFI program grants under Native Asset Building Initiative, with overall funding of approximately \$2,500,000 toward the initiative. It is anticipated that each recipient of these special AFI grants will also receive a separate ANA award for their project.

In addition to these special AFI awards, we estimate that \$15,000,000 in grants will be awarded in FY 2011 under the annual AFI funding opportunity announcement published on February 24, 2011.

Proposed Funding Opportunity Announcement; Native Asset Building Initiative

In FY 2011, OCS will coordinate with the Administration on Native Americans (ANA) on the Native Asset Building Initiative to support Tribes and Native organizations in planning and implementing comprehensive asset building projects. OCS and ANA are providing this support through a joint funding opportunity and training and technical assistance.

The OCS component of the joint funding opportunity will feature special Assets for Independence (AFI) program grants the eligibility for which will be limited to entities that are eligible for ANA grants. Therefore, eligibility for the special AFI grants will be limited to Native 501(c)(3) non-profits serving Native Americans; Federally recognized Tribal governments or Alaska Native Villages, as defined in the Alaska Native Claims Settlement Act, that are joint applicants with a 501(c)(3) Native non-profit organization; Native non-profit organizations designated by the Secretary of the Treasury as Community Development Financial Institutions and Native non-profit credit unions designated by the National Credit Union Administration as low-income credit unions that demonstrate a collaborative relationship with a local community-based organization whose activities are designed to address poverty and the needs of community members for economic independence and stability. Other entities will not be eligible to submit applications for the AFI grants under the Native Asset Building Initiative. It is estimated that OCS will award up to ten AFI program grants under the initiative, with overall funding of approximately \$2,500,000.

The ANA component of the Native Asset Building Initiative will feature a new funding opportunity through the Social and Economic Development Strategies (SEDS) program as well. The SEDS grants will provide funding for each project's operational and staffing costs, as well as support for financial literacy education training, capacity building, and other asset building activities.

The OCS AFI grants will provide funding to support the provision of Individual Development Accounts (IDA), or matched savings accounts, component of each selected applicant's comprehensive asset building project. The AFI grantees will also provide funding to support limited administrative costs related to the IDA component. AFI is a demonstration of the use of IDAs and related strategies

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.

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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;