

Furthermore, section 1874(b) of the Act authorizes the Secretary to "contract with any person, agency, or institution to secure on a reimbursable basis such special data, actuarial information, and other information as may be necessary in the carrying out of his functions" under this title (42 U.S.C. 1395kk(b)).

Section 1893 of the Act establishes the Medicare Integrity Program, under which the Secretary may contract with eligible entities to conduct a variety of program safeguard activities, including fraud review employing equipment and software technologies that surpass the existing capabilities of Fiscal Intermediaries and carriers (42 U.S.C. 1395ddd). The contracting entities are called Program Safeguards Contractors (PSC).

DPW is charged with the administration of the Medicaid program in Pennsylvania and is the single state agency for such purpose. 62 Purdon's Statutes (P.S.) § 201(1); 55 Pennsylvania (Pa.) Code § 101.1(e). In Pennsylvania, DPW provides qualifying individuals with health care and related remedial or preventive services, including both Medicaid services and services authorized under state law that are not provided under Federal law. The program to provide all such services is known as the Medical Assistance (MA) Program.

DPW's disclosure of the MA Program data pursuant to this Agreement is for purposes directly connected with the administration of the MA Program, in compliance with 62 P.S. § 404, 55 Pa. Code §§ 105.1 *et seq.*, 42 U.S.C. 1396a(a)(7), 42 CFR 431.300 *et seq.*, and 45 CFR 205.50–205.60. Those purposes include the investigation, prosecution or criminal or civil proceeding conducted in connection with the administration of the MA Program. (55 Pa. Code § 105.3(b)(2)).

**PURPOSE(S) OF THE MATCHING PROGRAM:**

The purpose of this Agreement is to establish the conditions, safeguards, and procedures under which the Centers for Medicare & Medicaid Services (CMS) will conduct a computer matching program with the Commonwealth of Pennsylvania, Department of Public Welfare (DPW), to study claims, billing, and eligibility information to detect suspected instances of Medicare and Medicaid fraud and abuse (F&A) in the Commonwealth of Pennsylvania. CMS and DPW will provide Electronic Data Systems (EDS), a CMS contractor (hereinafter referred to as the "Custodian"), with Medicare and Medicaid records pertaining to eligibility, claims, and billing which the Custodian will match in order to merge

the information into a single database. Utilizing fraud detection software, the information will then be used to identify patterns of aberrant practices requiring further investigation. The following are examples of the type of aberrant practices that may constitute F&A by practitioners, providers, and suppliers in the Commonwealth of Pennsylvania expected to be identified in this matching program: (1) Billing for provision of more than 24 hours of services in one day; (2) providing treatment and services in ways more statistically significant than similar practitioner groups; and (3) up-coding and billing for services more expensive than those actually performed.

**CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:**

This CMP will enhance the ability of CMS and DPW to detect F&A by matching claims data, eligibility, and practitioner, provider, and supplier enrollment records of Medicare beneficiaries, practitioners, providers, and suppliers in the Commonwealth of Pennsylvania against records of Pennsylvania Medicaid beneficiaries, practitioners, providers, and suppliers in the Commonwealth of Pennsylvania.

**DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:**

The data for DPW are maintained in the following data files:

The data the Pennsylvania Fraud and Abuse Detection System (FADS) receives consists of a number of data tables that contain the different data element requirements for the operation of the system. These tables are grouped into "universes" of data. In Phase I the FADS universes are: Claims Analysis, Provider, Recipient, Reference, and Code Tables. In Phase II they are: Claims Analysis, Provider, Recipient, Reference, Financial, and Managed Care.

**INCLUSIVE DATES OF THE MATCH:**

The CMP shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04-7633 Filed 4-2-04; 8:45 am]

**BILLING CODE 4120-03-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Community Food and Nutrition Program—Discretionary Grants; Office of Community Services**

*Announcement Type:* Initial.  
*Funding Opportunity Number:* HHS-2004-ACF-OCS-EN-0007.

*CFDA Number:* 93.571.

*Due Date for Applications:* Due date for receipt of applications is June 4, 2004.

**I. Funding Opportunity Description**

The Community Services Block Grant (CSBG) Act, as amended, authorizes the Secretary of Health and Human Services to make funds available under several programs to support program activities that will result in direct benefits targeted to low-income people. This program announcement covers the grant authority found at Section 681 of the Community Services Block Grant Act, (The Act) (Pub. L. 97-35) as amended by the Community Opportunities, Accountability, and Training and Educational Services Act of 1998 (Pub. L. 105-285), Community Food and Nutrition Program. The Act authorizes the Secretary to award grants on a competitive basis to eligible entities for community-based, local and statewide and national programs including programs benefiting Indians (as defined in section 677(e) of the CSBG Act) and migrant farm workers.

The main objective of the CFNP is to link low-income people to food and nutrition programs. Grant funds are provided to: (1) Coordinate private and public food assistance resources, wherever the grant recipient involved determines such coordination to be inadequate, to better serve low-income populations; (2) assist low-income communities to identify potential sponsors of child nutrition programs and to initiate such programs in underserved or unserved areas; and (3) develop innovative approaches at the State and local level to meet the nutrition needs of low-income individuals. The OCS views this program as a capacity building program, rather than a food delivery program.

The Office of Community Services encourages eligible applicants with programs addressing obesity to submit applications. Eligible applicants with programs benefiting Native Americans and migrant or seasonal farm workers are also encouraged to submit applications. Faith-based and

community-based organizations reaching underserved populations are also eligible to apply.

#### *Definitions of Terms*

The following definitions apply:

**Budget Period**—The interval of time into which a grant period of assistance (project period) is divided for budgetary and funding purposes.

**Capacity-Building**—Refers to activities that assist eligible entities to improve or enhance their overall or specific capability to plan, deliver, manage and evaluate programs efficiently and effectively to produce intended results for low-income individuals. This may include upgrading internal financial management or computer systems, establishing new external linkages with other organizations, adding or refining a program component or replicating techniques or a program piloted in another local community, or making other cost effective improvements.

**Displaced Worker**—An individual who is in the labor market but has been unemployed for six months or longer.

**Eligible Entity**—Public and private non-profit agencies, including organizations benefiting Indians and migrant and seasonal farmworkers. Faith-based organizations are eligible to apply for these Community Food and Nutrition Program grants. Community-based organizations are eligible to apply for these Community Food and Nutrition Program grants.

**Empowerment Zone and Enterprise Communities**—Those communities designated as such by the Secretary of Agriculture or the Secretary of Housing and Urban Development.

**Indian Tribe**—A tribe, band, or other organized group of Native American Indians recognized in the State or States in which it resides, or considered by the Secretary of the Interior to be an Indian tribe or an Indian organization.

**Innovative Project**—One that departs from, or significantly modifies, past program practices and tests a new approach.

**Migrant Farm Worker**—An individual who works in agricultural employment of a seasonal or other temporary nature who is required to be absent from his/her place of permanent residence in order to secure such employment.

**Poverty Income Guidelines**—Guidelines published annually by the U.S. Department of Health and Human Services that establish the level of poverty defined as low-income for individuals and their families. The guideline information is posted on the Internet at the following address: <http://www.hhs.aspe.gov/poverty/>

**Program Income**—Gross income earned by the grant recipient that is generated by an activity supported with grant funds.

**Project Period**—The total time for which a project is approved for support, including any approved extensions.

**Seasonal Farm Worker**—Any individual employed in agricultural work of a seasonal or other temporary nature who is able to remain at his/her place of permanent residence while employed.

**Self-Sufficiency**—A condition where an individual or family does not need, and is not eligible to receive, TANF assistance under Title I of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Part A of Title IV of the Social Security Act.)

**Underserved Area**—(as it pertains to child nutrition programs)—A locality in which less than one-half of the low-income children eligible for assistance participate in any child nutrition program.

**Non-profit Organization**—refers to an organization, including faith-based and community-based organization, which meets the requirement for proof of non-profit status in the “Additional Information on Eligibility” section of this announcement and has demonstrated experience in providing training to individuals and organizations on methods of effectively addressing the needs of low-income families and communities.

**Territories**—refers to the Commonwealth of Puerto Rico and American Samoa for the purpose of this announcement.

#### *Program Purpose, Scope and Focus*

The Department of Health and Human Services (DHHS) is committed to improving the overall health and nutritional well-being of all individuals, including low-income persons, through improved preventive health care and promotion of personal responsibility.

DHHS also recognizes that improving the health and nutrition status of low-income persons can also be improved by access to healthy, nutritious foods or by other means. DHHS encourages community efforts to improve the coordination and integration of health and social services for all low-income families, and to identify opportunities for collaborating with other programs and services for this population. Such collaboration can increase a community's capacity to leverage resources and promote an integrated approach to health and nutrition through existing programs and services.

Projects funded under this program must focus on one or more legislatively-

mandated program activities: (a) Coordination of private and public food assistance resources, wherever the grant recipient involved determines such coordination to be inadequate, to better serve low-income populations; (b) assistance to low-income communities in identifying potential sponsors of child nutrition programs and initiating such programs in unserved or underserved areas; and (c) development of innovative approaches at the state and local level to meet the nutrition needs of low-income individuals.

Additionally, in carrying out such activities, projects funded under this program should (1) be designed and intended to provide nutrition benefits, including those which incorporate the benefits of disease prevention, to a targeted low-income group of people; (2) provide outreach and public education to inform eligible low-income individuals and families of other nutritional services available to them under the various Federally-assisted programs; (3) carry out targeted communications and social marketing to improve dietary behavior and increase program participation among eligible low-income populations. Populations to be targeted can include displaced workers, elderly people, children, and the working poor, and (4) consult with and/or inform local officials that administer other food programs such as W.I.C. and Food Stamps, where applicable, to ensure effective coordination which can jointly target services to increase their effectiveness. Such consultation may include involving these offices in planning grant applications.

The OCS views this program as a capacity-building program, rather than a food delivery program. Applications proposing to use OCS funds solely to purchase food for low-income individuals may be considered non-responsive and be returned to the applicant without further review.

#### *Mobilization of Resources*

There is no match requirement for the Community Food and Nutrition Program. However, OCS would like to mobilize as many resources as possible to enhance projects funded under the CFNP. OCS supports and encourages applications submitted by applicants whose programs will leverage other resources, either cash or third party in-kind.

#### *Administrative Costs/Indirect Costs*

There is no predetermined administrative cost ceiling for projects funded under this program. Indirect costs consistent with approved indirect

cost rate agreements are allowable. Applicants should enclose a copy of the current approved rate agreement. However, it should be understood that indirect costs are part of, and not in addition to, the amount of funds awarded in the subject grant.

#### *Multiple Submittals*

There is no limit to the number of applications that can be submitted by an eligible applicant as long as each application is for a different project. However, no applicant will receive more than one grant.

#### *Repeat Grantee*

Applicants receiving OCS funds for CFNP projects completed within the last five (5) years must submit with the application an abstract for each such project. The abstract should include the applicant's name, address, CFNP grant number and amount, the title of the project, and a summary of accomplishments. An application that does not include an abstract for each project previously funded may be considered non-responsive and be returned to the applicant without further review.

#### *Priority Area:*

There is one Program Priority Area for Fiscal Year 2004: Priority Area 1.0—General Projects, under which OCS will accept applications as described below.

#### *Priority Area 1.0—General Projects*

The application should describe the target area and population to be served and discuss the nature and extent of the problem to be solved. The application must contain a detailed and specific work program that is sound and feasible. Projects funded under this announcement must produce lasting and measurable results that fulfill the purposes of this program as described above. The OCS grant funds, in combination with private and/or other public resources, must be targeted to low-income individuals and communities.

Applicants will certify in their submission that projects will only serve the low-income population as stipulated in the DHHS Poverty Income Guidelines. The guideline information is posted on the Internet at the following address: <http://www.hhs.aspe.gov/poverty/>. Failure to comply with the DHHS Poverty Income Guidelines may result in the application not being considered for funding.

If an applicant proposes a project that will affect a property listed in, or eligible for, inclusion in the National Register of Historic Places, it must identify this property in the narrative

and explain how it has complied with the provisions of Section 106 of the National Historic Preservation Act of 1966, as amended. If there is any question as to whether the property is listed in, or is eligible for inclusion in, the National Register of Historic Places, applicant should consult with the State Historic Preservation Officer. The applicant should contact OCS early in the development of its application for instructions regarding compliance with the Act and data required to be submitted to DHHS.

When projects propose to mobilize or improve the coordination of existing public and private food assistance resources, the guidelines governing those resources apply. However, when projects propose to provide direct assistance to beneficiaries through grants funded under this program, those beneficiaries must fall within the official DHHS Poverty Income Guidelines.

Applications proposing the use of grant funds to develop printed or visual materials must contain convincing evidence that these materials are not available from other sources. The OCS will not provide funding for such items if justification is not sufficient. Approval of any films or visual presentations proposed by applicants approved for funding will be made part of the grant award. When material outlays for equipment (audio and visual) are requested, specific evidence must be presented that there is a definite programmatic connection between the equipment (audio and visual) usage and the outreach requirements described in the Program Purpose, Scope and Focus section of this announcement.

## **II. Award Information**

*Funding Instrument Type:* Service Grant.

*Anticipated Total Priority Area Funding:* \$2,400,000.

*Anticipated Number of Awards:* 48–52.

*Ceiling on Amount of Individual Awards:* \$50,000.

An application that exceeds \$50,000 will be considered “non-responsive” and be returned to the applicant without further review.

*Floor of Individual Award Amounts:* None.

*Average Projected Award Amount:* \$50,000.

*Project Period for Grants:* 12 Months.

## **III. Eligibility Information**

### *1. Eligible Applicants*

Nonprofits having a 501 (c) (3) status with the IRS, other than institutions of

higher education Nonprofits that do not have a 501 (c) (3) status with the IRS, other than institutions of higher education

#### *Additional Information on Eligibility*

Eligible applicants are public and private nonprofit agencies including organizations benefiting Indians and migrant and seasonal farmworkers with a demonstrated ability to successfully develop and implement programs and activities similar to those enumerated in the announcement. Faith-based organizations and community-based organizations are eligible to apply for these Community Food and Nutrition Program grants. Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission.

Proof of non-profit status is any one of the following:

(a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code.

(b) A copy of a currently valid IRS tax exemption certificate.

(c) A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.

(d) A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

(e) Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

The Office of Community Services encourages eligible applicants with programs addressing obesity to submit applications. Eligible applicants with programs benefiting Native Americans and migrant or seasonal farm workers are also encouraged to submit applications. Faith-based and community-based organizations reaching underserved populations are also encouraged to apply.

Private non-profit organizations are encouraged to submit with their applications the survey located under “Grant Related Documents and Forms” titled “Survey for Private, Non-Profit Grant Applicants” at <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

## 2. Cost Sharing or Matching

Cost sharing or matching funds are not required for applications submitted under this program announcement.

## 3. Other

All applicants must have a Dun & Bradstreet Number. On June 27, 2003, the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires all Federal grant applicants to provide a Dun & Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (<http://www.Grants.gov>). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1-866-705-5711 or you may request a number on-line at <http://www.dnb.com>.

## IV. Application and Submission Information

### 1. Address to Request Application Package

Catherine Rivers, Administration for Children and Families, Office of Community Services' Operations Center, 1815 Fort Myer Drive, Suite 300, Arlington, Virginia 22209, Email: [OCS@lcgnet.com](mailto:OCS@lcgnet.com) Attention: Catherine Rivers, Telephone: 1-800-281-9519.

### 2. Content and Form of Application Submission

#### 1. Application Content

An original and two copies of each application are required. Each application must include the following components:

1. Table of Contents.
2. Abstract of the Proposed Project—very brief, not to exceed 250 words, that would be suitable for use in an announcement that the application has been selected for a grant award and which identifies the type of project, the target population and the major elements of the work plan.
3. Completed Standard Form 424—that has been signed by an Official of the organization applying for the grant

who has authority to obligate the organization legally.

4. Standard Form 424A—Budget Information-Non-Construction Programs.

5. Narrative Budget Justification—for each object class category required under Section B, Standard Form 424A. Applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts for individuals specified in the application budget.

6. Project Narrative—A narrative that addresses issues described in the "Application Review Information" section of this announcement.

#### 2. Application Format

Submit application materials on white 8½ x 11 inch paper only. Do not use colored, oversized or folded materials.

Please do not include organizational brochures or other promotional materials, slides, films, clips, etc.

The font size may be no smaller than 12 pitch and the margins must be at least one inch on all sides.

Number all application pages sequentially throughout the package, beginning with the abstract of the proposed project as page number one.

Please present application materials either in loose-leaf notebooks or in folders with pages two-hole punched at the top center and fastened separately with a slide paper fastener.

#### 3. Page Limitation

The application package including sections for the Table of Contents, Project Abstract, Project and Budget Narratives must not exceed 30 pages. The page limitation does not include the following attachments and appendices: Standard Forms for Assurances, Certifications, Disclosures and appendices. The page limitation also does not apply to any supplemental documents as required in this announcement.

#### 4. Required Standard Forms

Applicants requesting financial assistance for a non-construction project must sign and return Standard Form 424B, Assurances: Non-Construction Programs with their applications.

Applicants must provide a Certification Regarding Lobbying. Prior to receiving an award in excess of \$100,000, applicants shall furnish an executed copy of the lobbying certification. Applicants must sign and return the certification with their application.

Applicants must make the appropriate certification of their compliance with the requirements of the Pro-Children

Act of 1994 as outlined in Certification Regarding Environmental Tobacco Smoke.

### 3. Submission Date and Times

The closing time and date for receipt of applications is 4:30 p.m. Eastern Standard Time (EST) on June 4, 2004. Mailed or hand carried applications received after 4:30 p.m. on the closing date will be classified as late.

**Deadline:** Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operations Center, 1815 Fort Myer Drive, Suite 300, Arlington, Virginia 22209 Attention: Barbara Ziegler-Johnson. Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date.

Applications hand carried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., EST, at the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services' Operations Center, 1815 Fort Myer Drive, Suite 300, Arlington, Virginia 22209 Attention: Barbara Ziegler-Johnson between Monday and Friday (excluding Federal holidays). This address must appear on the envelope/package containing the application with the note: "Attention: Barbara Ziegler-Johnson". Applicants are cautioned that express/overnight mail services do not always deliver as agreed.

**Late applications:** Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

**Extension of deadlines:** ACF may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mails service. Determinations to extend or waive deadline requirements rest with the Chief Grants Management Officer.

Pre-applications or letters of intent will not be accepted.

REQUIRED FORMS

What to submit	Required content	Required form or format	When to submit
Table of Contents .....	As described above .....	Consistent with guidance in "Application Format" section of this announcement.	By application due date.
Abstract of Proposed Project .....	Brief abstract that identifies the type of project, the target population and the major elements of the proposed project.	Consistent with guidance in "Application Format" section of this announcement.	Do.
Completed Standard Form 424 .....	As described above and per required form.	May be found on <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	Do.
Completed Standard Form 424A ...	As described above and per required form.	May be found on <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	Do.
Narrative Budget Justification .....	As described above .....	Consistent with guidance in "Application Format" section of this announcement.	Do.
Project Narrative .....	A narrative that addresses issues described in the "Application Review Information" section of this announcement.	Consistent with guidance in "Application Format" section of this announcement.	Do.
Completed Standard Form 424B ...	As described above and per required form.	May be found on <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	Do.
Certification Regarding Lobbying ...	As described above and per required form.	May be found on <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	Do.
Certification Regarding Environmental Tobacco Smoke.	As described above and per required form.	May be found on <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	Do.

*Additional Forms:* Private-non-profit organizations may submit with their applications the additional survey located under "Grant Related Documents and Forms" titled "Survey for Private, Non-Profit Grant Applicants" for Applicants".

Survey for Private, Non-Profit Grant Applicants.	As described above and per required form.	May be found on <a href="http://www.acf.hhs.gov/programs/ofs/forms.htm">http://www.acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.
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4. Intergovernmental Review

State Single Point of Contact (SPOC)

This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. As of October 1, 2003, the following jurisdictions have elected not to participate in the Executive Order process. Applicants from these jurisdictions or for projects administered by federally-recognized Indian Tribes need take no action in regard to E.O. 12372:

All States and Territories except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma,

Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, Wyoming and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-five jurisdictions need take no action.

Although the jurisdictions listed above no longer participate in the process, entities which have met the eligibility requirements of the program are still eligible to apply for a grant even if a State, Territory, Commonwealth, etc. does not have a SPOC. All remaining jurisdictions participate in the Executive Order process and have established SPOCs. Applicants from participating jurisdictions should contact their SPOCs as soon as possible to alert them of the prospective applications and receive instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. The applicant

must submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Washington, DC 20447.

A list of the Single Points of Contact for each State and Territory is included with the application materials for this announcement.

#### 5. Funding Restrictions

Signed SF-424, SF-424A, and SF-424B

The application must contain a signed Standard Form 424 Application for Federal Assistance "SF-424", a Standard Form 424-A Budget Information "SF-424A" and signed Standard Form 424B Assurance—Non-Construction Programs "SF-424B" completed according to instructions provided in this Program Announcement.

#### Proof of Non-Profit Status

The application must contain documentation of the applicant's tax-exempt status as indicated in the "Additional Information on Eligibility" section of this announcement.

#### Project Narrative

The application must include a project narrative that meets requirements set forth in this announcement.

#### Capacity-Building Program

The OCS views this program as a capacity-building program, rather than a food delivery program. Applications proposing to use OCS funds solely to purchase food for low-income individuals may be considered non-responsive and be returned to the applicant without further review.

#### Program Beneficiaries

Projects proposed for funding under this announcement must result in direct benefits targeted toward low-income people as defined in the most recent annual update of the Poverty Income Guidelines published by DHHS. The guideline information is posted on the Internet at the following address: <http://www.hhs.aspe.gov/poverty/>. Annual revisions of these guidelines are normally published in the **Federal Register** in February or early March of each year and are applicable to projects being implemented at the time of publication. Grantees will be required to apply the most recent guidelines throughout the project period. The **Federal Register** may be obtained from public libraries, Congressional offices, or by writing the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. The **Federal Register** is also available on the Internet through GPO Access at the following web address: [http://www.access.gpo.gov/su\\_docs/aces/aces140.html](http://www.access.gpo.gov/su_docs/aces/aces140.html).

No other government agency or privately defined poverty guidelines are applicable to determining low-income eligibility for this OCS program.

#### Sub-Contracting or Delegating Projects

OCS will not fund any project where the role of the applicant is primarily to serve as a conduit for funds to organizations other than the applicant. The applicant must have a substantive role in the implementation of the project for which funding is requested. This prohibition does not bar the making of sub-grants or sub-contracting for specific services or activities needed to conduct the project.

#### Number of Projects in Application

Each application may include only one proposed project. Applications not complying with this requirement will be considered "non-responsive" and be returned to the applicant without further review.

#### Page Limitation

The application package including sections for the Table of Contents, Project Abstract, Project and Budget Narratives must not exceed 30 pages. The page limitation does not include the following attachments and appendices: Standard Forms for Assurances, Certifications, Disclosures and appendices. The page limitation also does not apply to any supplemental documents as required in this announcement.

#### Maximum Grant Amount

An application that exceeds \$50,000—the ceiling on the amount of an individual award—will be considered "non-responsive" and be returned to the applicant without further review.

#### Repeat Grantee

Applicants receiving OCS funds for CFNP projects completed within the last five (5) years must submit with the application an abstract for each such project. The abstract should include the applicant's name, address, CFNP grant number and amount, the title of the project, and a summary of accomplishments. An application that does not include an abstract for each project previously funded may be considered non-responsive and be returned to the applicant without further review.

#### 6. Other Submission Requirements

##### Electronic Copy Address Submission

You may submit your application to us in either electronic or paper format. To submit an application electronically,

please use the <http://www.Grants.gov> apply site. If you use Grants.gov, you will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to us.

Please note the following if you plan to submit your application electronically via Grants.gov

- Electronic submission is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.
  - To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.
    - You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.
    - You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.
    - Your application must comply with any page limitation requirements described in this program announcement.
      - After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. The Administration for Children and Families will retrieve your application from Grants.gov.
      - We may request that you provide original signatures on forms at a later date.
      - You may access the electronic application for this program on <http://www.Grants.gov>.
      - You must search for the downloadable application package by the CFDA number (93.571).

#### V. Application Review Information

##### 1. Criteria

*Paperwork Reduction Act of 1995 (Public Law 104-13)*: Under the Paperwork Reduction Act of 1995, Pub. L. 104-13, the Department is required to submit to the Office of Management and Budget (OMB) for review and approval of any reporting and record keeping requirements in regulations including program announcements. This program announcement does not contain

information collection requirements beyond those approved for ACF grant applications under the Program Narrative Statement by OMB No. 0970-0139.

Public reporting burden for this collection is estimated to average 25 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection of information. The project description is approved under OMB control #0970-0139 which expires 3/31/04.

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.

#### Purpose

The project description provides a major means by which an application is evaluated and ranked to compete with other applications for available assistance. The project description should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included where they can present information clearly and succinctly. In preparing your project description, all information requested through each specific evaluation criteria should be provided. Awarding offices use this and other information in making their funding recommendations. It is important, therefore, that this information be included in the application.

#### Introduction

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions and the specified evaluation criteria. The instructions give a broad overview of what your project description should include while the evaluation criteria expands and clarifies more program-specific information that is needed.

#### Project Summary/Abstract

Provide a summary of the project description (a page or less) with reference to the funding request.

#### Objectives and Need for Assistance

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as

letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

#### Results or Benefits Expected

Identify the results and benefits to be derived. For example, describe the population to be served by the program and the number of new jobs that will be targeted to the target population. Explain how the project will reach the targeted population, how it will benefit participants including how it will support individuals to become more economically self-sufficient.

#### Approach

Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates. If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF."

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

#### Organizational Profiles

Provide information on the applicant organization(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission.

The non-profit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code, or by providing a copy of the currently valid IRS tax exemption certificate, or by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

#### Budget and Budget Justification

Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF-424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

#### Evaluation Criterion I. Results or Benefits Expected (Maximum: 30 points)

##### I(a) Improvement in Nutrition Services to Low-Income People (0-15 Points)

The application will be evaluated on the extent to which it proposes to significantly improve or increase nutrition services to low-income people and indicate how such improvements or increases are quantified.

##### I(b) Promotional Health and Social Service Activities Included in Nutrition Services (0-5 Points)

The application will be evaluated on the extent to which it incorporates into

the project awareness of health and social services activities for low-income people along with nutritional services.

**I(c) Commitment of Resources (0–5 Points)**

The application will be evaluated on the extent to which it indicates that the project will significantly leverage or mobilize other community resources. These resources are detailed and quantified.

**I(d) One Time Funding (0–5 Points)**

The application will be evaluated on the extent to which it demonstrates either that the project addresses problem(s) that can be resolved by one-time OCS funding, or demonstrates that non-Federal funding is available to continue the project without Federal support.

In addressing the above criterion, the application must include quantitative data for items (a), (b), and (c), and discuss how the beneficial impact relates to the relevant legislatively-mandated program activities identified in the Program Purpose, Scope and Focus section of this announcement, and the problems and/or needs described under Criterion I.

**Evaluation Criterion II. Approach (Maximum: 25 points)**

**II(a) Realistic Quarterly Time Lines (0–10 Points)**

The application will be evaluated on the extent to which it provides realistic quarterly projections of the activities to be carried out including the projected number of beneficiaries to be served each quarter.

**II(b) Detailed Work Plan (0–15 Points)**

The application will be evaluated on the extent to which it ensures that activities are adequately described and appear reasonably likely to achieve results which will have a desired impact on the identified problems and/or needs. In addressing this criterion, the application should address the basic criteria and other mandated activities found in Parts A and B and should include:

(1) Project priorities, and rationale for selecting them, which relate to the specific nutritional problem(s) and/or need(s) of the target population identified under Criterion I;

(2) Goals and objectives that speak to the problem(s) and/or need(s); and

(3) Project activities that, if successfully carried out, can reasonably be expected to result in achieving these goals and objectives.

**Evaluation Criterion III. Organizational Profiles (Maximum: 15 points)**

**III(a) Organizational Experience in Program Area (0–5 Points)**

The application will be evaluated on the extent to which it documents the organization's capability and relevant experience in developing and operating programs that deal with poverty problems similar to those to be addressed by the proposed project. Documentation provided should indicate that projects previously undertaken have been relevant and effective and have provided permanent benefits to the low-income population. Organizations proposing training and technical assistance should have detailed competence in the program area and expertise in training and technical assistance. If applicable, information provided in these applications should also address related achievements and competence of each cooperating or sponsoring organization.

**III(b) Management History (0–5 Points)**

The application will be evaluated on the extent to which it demonstrates the applicant's ability to implement sound and effective management practices. If the applicant has been a recipient of other Federal or other governmental grants, it must also document their compliance with financial and program progress reporting and audit requirements. Such documentation may be in the form of references to any available audit or progress reports and should be accompanied by a statement from a Certified or Licensed Public Accountant as to the sufficiency of the applicant's financial management system to protect adequately any Federal funds awarded under the application submitted.

**III(c) Staff Skills, Resources and Responsibilities (0–5 Points)**

The application will be evaluated on the extent to which it adequately describes the experience and skills of the proposed Project Director, showing that the individual is not only well qualified, but that his/her professional capabilities are relevant to successfully implement the project. If the key staff person has not yet been identified, the application should contain a comprehensive position description indicating that the responsibilities to be assigned to the Project Director are relevant to successfully implement the project. The application must indicate that it has adequate facilities and resources (*i.e.* space and equipment) to carry out the work plan successfully.

In addressing the above criterion, the application must clearly show that sufficient time of the Project Director and other senior staff will be budgeted to assure timely project implementation and oversight and that the assigned responsibilities of the staff are appropriate to the tasks identified.

**Evaluation Criterion IV. Objectives and Need for Assistance (Maximum: 10 points)**

**IV(a) Description of Target Population. (0–4 Points)**

The application will be evaluated on the extent to which it describes the target area and population to be served, including specific details on any minority population(s) to be served.

**IV(b) Analysis of Needs/Priorities (0–6 Points)**

The application will be evaluated on the extent to which it discusses the nature and extent of the problem(s) and/or need(s), including specific information on minority population(s).

**Evaluation Criterion V. Approach: Coordination/Services Integration (Maximum: 10 Points)**

**V(a) Coordinated Community-Based Planning (0–5 Points)**

The application will be evaluated on the extent to which it demonstrates evidence of coordinated community-based planning in its development, including strategies in the work program to collaborate with other locally-funded Federal programs (such as DHHS health and social services and USDA Food and Consumer Service programs) in ways that will eliminate duplication and will, for example: (a) Unite funding streams at the local level to increase program outreach and effectiveness; (b) facilitate access to other needed social services by coordinating and simplifying intake and eligibility certification processes for clients; or (c) bring project participants into direct interaction with holistic family development resources in the community where needed.

**V(b) Community Empowerment Consideration (0–5 Points)**

Special consideration will be given to applications located in areas characterized by poverty and other indicators of socio-economic distress such as a poverty rate of at least 20 percent, designation as an Empowerment Zone or Enterprise Community, high levels of unemployment, and high levels of incidences of violence, gang activity, crime, or drug use. The application will be evaluated on the extent to which it

documents involvement in the preparation and planned implementation of a comprehensive community-based strategic plan to achieve both economic and human development in an integrated manner. If the applicant is receiving funds from the State for community food and nutrition activities, the application should address how the funds are being utilized, and how they will be coordinated with the proposed project to maximize the effectiveness of both. If State funds are being used in the project for which OCS funds are being requested, the application should specifically describe their usage.

Evaluation Criterion VI. Budget and Budget Justification (Maximum: 10 Points)

VI(a) Budget and Budget Justification (0–10 Points)

Every application must include a Budget Justification, placed after the budget forms SF-424 and 424A, explaining the sources and uses of project funds. The budget is adequate and administrative costs are appropriate to the services proposed.

## 2. Review and Selection Process

### Initial OCS Screening

Each application submitted to OCS will be screened to determine whether it was received by the closing date and time.

Applications received by the closing date and time will be screened for completeness and conformity with the following requirements. Only complete applications that meet the requirements listed below will be reviewed and evaluated competitively. Other applications will be returned to the applicants with a notation that they were unacceptable and will not be reviewed.

All applications must comply with the following requirements except as noted:

(a) The application must contain a signed Standard Form 424 Application for Federal Assistance “SF-424”, a Standard Form 424-A Budget Information “SF-424A” and signed Standard Form 424B Assurance—Non-Construction Programs “SF-424B” completed according to instructions provided in this Program Announcement. The forms SF-424 and the SF-424B must be signed by an official of the organization applying for the grant who has authority to obligate the organization legally. The applicant’s legal name as required on the SF-424 (Item 5) must match that listed as

corresponding to the Employer Identification Number (Item 6);

(b) The application must include a project narrative that meets requirements set for in this announcement.

(c) The application must contain documentation of the applicant’s tax-exempt status as indicated in the “Additional Information on Eligibility” section of this announcement.

(d) The application package including sections for the Table of Contents, Project Abstract, Project and Budget Narratives must not exceed 30 pages. The page limitation does not include the following attachments and appendices: Standard Forms for Assurances, Certifications, Disclosures and appendices. The page limitation also does not apply to any supplemental documents as required in this announcement. An application package that exceeds the page limitation will be considered “non-responsive” and be returned to the applicant without further review.

(e) An application that exceeds \$50,000—the ceiling on the amount of an individual award—will be considered “non-responsive” and be returned to the applicant without further review.

(f) Private, non-profit organizations are encouraged to submit with their applications the optional survey located under “Grants Manuals & Forms” at: <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

### OCS Evaluation of Applications

Applications that pass the initial OCS screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this program announcement.

The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application. The review panel awards points only to applications that are responsive to the program elements and relevant review criteria within the context of this program announcement.

The OCS Director and program staff use the reviewer scores when considering competing applications. Reviewer scores will weigh heavily in funding decisions, but will not be the only factors considered.

Applications generally will be considered in order of the average scores assigned by the review panel. Because other important factors are taken into consideration, highly ranked

applications are not guaranteed funding. These other considerations include, for example: the timely and proper completion by the applicant of projects funded with OCS funds granted in the last five (5) years; comments of reviewers and government officials; staff evaluation and input; amount and duration of the grant requested and the proposed project’s consistency and harmony with OCS goals and policy; geographic distribution of applications; previous program performance of applicants; compliance with grant terms under previous HHS grants, including the actual dedication to program of mobilized resources as set forth in project applications; audit reports; investigative reports; and applicant’s progress in resolving any final audit disallowance on previous OCS or other Federal agency grants.

3. *Anticipated Announcement and Award Dates*: 90 days after the due date of applications.

## VI. Award Administration Information

1. *Award Notices*: Successful applicants will be notified through the issuance of a Financial Assistance Award notice that sets forth the amount of funds granted, the terms and conditions of the grant award, the effective date of the award, the budget period for which initial support is given, and the total project period for which support is provided. The Financial Assistance Award will be signed by a Grants Officer and transmitted via postal mail. Unsuccessful applicants will be notified in writing by ACF.

2. *Administrative and National Policy Requirements*: 45 CFR Part 74.

*Special Terms and Conditions of Awards*: None.

### 3. Reporting Requirements

*Programmatic Reports*: Semi-annually and a final report is due 90 days after the end of the grant period.

*Financial Reports*: Semi-annually and a final report is due 90 days after the end of the grant period.

*Special Reporting Requirements*: None.

## VII. Agency Contacts

*Program Office Contact*: Catherine Rivers, Administration for Children and Families, Office of Community Services’ Operations Center, 1815 Fort Myer Drive, Suite 300, Arlington, Virginia 22209, Email: [OCS@cgnet.com](mailto:OCS@cgnet.com) Attention: Catherine Rivers, Telephone: 1-800-281-9519.

*Grants Management Office Contact*: Barbara Ziegler-Johnson, Office of Grants Management, Division of

Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447-0002. Email: [OCS@icgnet.com](mailto:OCS@icgnet.com). Telephone: 1-800-281-9519.

### VIII. Other Information

Additional Information about this program and its purpose can be located on the following Web site: <http://www.acf.hhs.gov/programs/ocs>.

Dated: March 30, 2004.

**Clarence H. Carter,**

*Director, Office of Community Services.*

[FR Doc. 04-7609 Filed 4-2-04; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0132]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for premarket approval of medical devices.

**DATES:** Submit written or electronic comments on the collection of information by June 4, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Premarket Approval of Medical Devices—21 CFR Part 814 (OMB Control Number 0910-0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either preamendments devices that have been classified into class III, postamendments devices which are not substantially equivalent to a preamendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, or devices which otherwise present a potentially unreasonable risk of illness or injury, or are of substantial importance in preventing impairment of human health. Most premarket approval

application (PMAs) are for postamendments class III devices.

Under section 515 of the act, an application must contain several pieces of information including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties and of the principle or principles of operation of such a device and should also include a full description of the methods used in, and the facilities and controls used for the manufacture and processing of the device; and labeling specimens.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a class III medical device and the criteria FDA employs in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulation's purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval) medical devices. The regulations contained in part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the disapproval of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105-115) was enacted on November 21, 1997, to implement revisions to the act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several provisions of this act affect the PMA process, such as section 515(d)(6) of the act. This section provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, in the past 3 years FDA has done the following: Made changes to the PMA program based on comments received, complied with changes to the program mandated by FDAMA, and worked towards completion of its PMA reinvention efforts.