

- Procurement assistance, review/recommendations for current contract processes to include, contract reform, technical guidance, price and cost estimating, and source selection evaluation support.
- Organizational planning including functional and gap analysis.
- Research and development, assessment of new technologies and advice on medical and technical innovation and health information.
- Continuous process improvement, Investment Life Cycle (ILC)/current practices review and recommendations, implementation of best practices and code reviews.
- IV&V/Compliance, DUA surveillance and Web site content review.
- Security including Security Assessments and Security Test and Evaluations (ST&E). Identify, define, and resolve problems as an integral part of the sponsor's management team.
- Providing independent analysis about DHHS vulnerabilities and the effectiveness of systems deployed to make DHHS more effective in providing healthcare services and implementation of new healthcare initiatives.
- Providing intra-departmental and inter-agency cross-cutting, risk-informed analysis of alternative resource approaches.
- Developing and deploying analytical tools and techniques to evaluate system alternatives (for example, policy-operations-technology tradeoffs), and life-cycle costs that have broad application across CMS.
- Developing measurable performance metrics, models, and simulations for determining progress in securing DHHS data or other authorized data sources, (non-DHHS data sources, such as the census data or Department of Labor data, Veterans Administration, Department of Defense, data in developing performance metrics, and models).
- Providing independent and objective operational test and evaluation analysis support.
- Developing recommendations for guidance on the best practices for standards, particularly to improve the inter-operability of DHHS components.
- Assessing technologies and evaluating technology test-beds for accurate simulation of operational conditions and delivery system innovation models.
- Supporting critical thinking about the DHHS enterprise, business intelligence and analytic tools that can be applied consistently across DHHS and CMS programs.

- Supporting systems integration, data management, and data exchange that contribute to a larger DHHS intra and inter-agency enterprise as well as collaboration with States, local tribal governments, the business sector (for-profit and not-for-profits), academia and the public.
- Providing recommendations for standards for top-level DHHS systems requirements and performance metrics best practices for an integrated DHHS approach to systems solutions and structured and unstructured data architecture.
- Understanding key DHHS organizations and their specific role and major acquisition requirements and support them in the requirements development phase of the acquisition lifecycle.
- The FFRDC must function so effectively as to act as an agent for the sponsor in the design and pursuit of mission goals.
- The FFRDC must provide rapid responsiveness to changing requirements for personnel in all aspects of strategic, technical and program management.
- The FFRDC must recognize government objectives as its own objectives, partnering with the sponsor in pursuit of excellence in public service.
- The FFRDC must allow for non-sponsor (other than CMS) work for operating Divisions within DHHS.

We are publishing this notice in accordance with 48 CFR 5.205(b) of the FAR, to enable interested members of the public to provide comments on this proposed action. We note that this is the third of three notices issued under the FAR.

The Request for Proposal will be posted on FedBizOpps in the Summer of 2011. Alternatively, a copy can be received by contacting the person listed in the **"FOR FURTHER INFORMATION CONTACT"** section above.

Dated: June 8, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Voluntary Agencies Matching Grant Program.

OMB No.: New.

Description: The Voluntary Agencies Matching Grant Program was initiated in 1979 as an early employment alternative to public cash assistance. The goal of the Matching Grant Program is to assist individuals eligible for ORR funded services in attaining economic self-sufficiency within 120 to 180 days from their date of eligibility. Self-sufficiency must be achieved without accessing public cash assistance.

With the projected expansion of the Voluntary Agencies Matching Grant Program to 11 grantees in FY 2012, the Office of Refugee Resettlement (ORR) intends to seek approval from Office of Management and Budget (OMB) for information collection associated with the program. This includes a pre-award template for each local service provider site location and the data points the program currently collects.

The Local Service Provider Site Project Design template provides ORR with the information necessary to evaluate the appropriateness of the service delivery according to the capacity of the service provider to deliver required services and the potential of those enrolled in the program to achieve self-sufficiency. The collection instrument is a template composed of a ½ page table with contact and capacity data, a narrative of up to 2½ pages covering 11 elements related to capacity and service delivery, and a line-item budget. This form is required as part of the initial grant application and with each annual award renewal.

The Data points are aggregate measures for each site where Matching Grant Program services are provided. The data points will be collected using SF-PPR D. ORR has found these data points to be essential for evaluating grantee and program performance in meeting the requirements of both the Refugee Act and ORR regulations. Data points are recorded at enrollment and 120 days and/or 180 days from the point when the enrolled individual became eligible for the program. Data points include, eligible immigration status, employment eligibility and status, wage level, reasons for dropping out of the program (if applicable), and self-

sufficiency outcomes. Grantees report data points to ORR triennially (every four-months) and annually.

Respondents: Voluntary agencies that already provide Reception & Placement services through a cooperative

agreement with the U.S. Department of State (DOS) or the U.S. Department of Homeland Security (DHS).

ANNUAL BURDEN ESTIMATES

Instruments	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Local Service Provider Site Project Design Template	11	21.90	1	240.90
SF PPR D Spreadsheet	11	1	1.10	12.10

Estimated Total Annual Burden Hours: 253

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address:* infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0530]

Draft Guidance for Industry; Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology". This guidance is intended to provide industry with FDA's current thinking on whether FDA-regulated products contain nanomaterials or otherwise involve the application of nanotechnology. The points to consider are intended to be broadly applicable to all FDA-regulated products, with the understanding that additional guidance may be articulated for specific product areas, as appropriate in the future.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 15, 2011.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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: Ritu Nalubola, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4236, Silver Spring, MD 20993-0002, 301-796-4830, *e-mail:* Ritu.Nalubola@fda.hhs.gov; or Carlos Peña, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4264, Silver Spring, MD 20993-0002, 301-796-4880, *e-mail:* Carlos.Pena@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology". The guidance is intended for manufacturers, suppliers, importers, and other stakeholders. The guidance describes FDA's current thinking on whether FDA-regulated products contain nanomaterials or otherwise involve the application of nanotechnology. As a first step toward developing FDA's framework for considering whether FDA-regulated products include nanomaterials or otherwise involve nanotechnology, the Agency has developed the points discussed in the guidance. These points to consider are intended to be broadly applicable to all FDA-regulated products, with the understanding that additional guidance may be articulated for specific product areas, as appropriate in the future. The guidance document does not establish any regulatory definitions. Rather, it is intended to help industry and others identify when they should consider potential implications for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology in FDA-regulated products. Public input on the