economic stability, foster responsible parenting, and promote healthy marriage. Program designs that include case management, and support services that can facilitate program participation and improved effectiveness, were strongly encouraged. Finally, funding under this program also supports comprehensive and effective employment services, including subsidized employment.

Statutory Authority: The award is made under the authority of Claims Resettlement Act of 2010 (Pub. L. 111–291).

Susan Golonka,

Deputy Director, Office of Family Assistance, Administration for Children and Families.

[FR Doc. 2012–25561 Filed 10–16–12; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.086]

Announcement of the Award of a Single-Source Program Expansion Supplement to One Grantee Under the Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Pilot Project Grants

AGENCY: Office of Family Assistance, ACF, HHS.

ACTION: Announcement of the award of a single-source program expansion supplement to The RIDGE Project in Defiance, OH to support the Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Pilot Project activities that promote responsible fatherhood through the provision of subsidized employment, family reunification, and economic stability services to formerly incarcerated fathers designed to move individuals and families to self-sufficiency.

SUMMARY: The Administration for Children and Families (ACF), Office of Family Assistance (OFA), Division of State and Territory TANF Management (DSTTM) announces the award of a single-source program expansion award of $131,666 to The RIDGE Project in Defiance, OH.

The RIDGE Project is a 501(c)(3), faith-based organization founded in 2000 and provides a broad range of services in Ohio to over 30,000 individuals a year with over 100,000 units of service each year. Their mission is to strengthen families through youth development, marriage and fatherhood programs, workforce development, and reentry programs designed to equip people to achieve social and economic self-sufficiency. Activities include the provision of economic stability, subsidized employment, and supportive services. Upon release from prison, participants continue in the program and are served by The RIDGE Project or one of its regional partners.

The primary purpose is to eliminate barriers for fathers to achieve social and economic self-sufficiency through subsidized employment for individuals preparing to reenter their communities or those who have recently returned to their communities following incarceration. The RIDGE Project also implements three legislatively specified activities: Healthy marriage, responsible parenting, and economic stability.

The program expansion supplement will support the project's culinary arts training and employment, designed to prepare program participants for careers in the culinary field. According to recent data from the *People Report Workforce Index,* which surveys restaurant human resources departments and recruiters on trends in employment, continued job growth is anticipated in the food service industry, with high levels of recruiting difficulty, and a rise in vacancies/turnovers expected. Employers are reporting that though they have hundreds of applicants, they are finding it increasingly difficult to find employees with the right skill set.

The RIDGE Project will begin offering an 8-week Culinary Arts training to formerly incarcerated fathers who have successfully completed their flagship responsible fatherhood and economic stability program and have evidenced their commitment to responsible fatherhood and show an aptitude and interest in the food service industry.

The program will provide students with the basic skills necessary to function in an entry-level capacity in a restaurant or commercial kitchen. Successful students will complete the program having achieved the ServSafe™ Certification, and will have demonstrated the core skills necessary to begin work in food preparation or as a line cook entrance chef. Finally, upon satisfactory completion, The RIDGE Project's Workforce Development Department will function to assist the fathers with job placement, including subsidized wages in local restaurants.

DATES: September 30, 2012–September 29, 2013.

FOR FURTHER INFORMATION CONTACT: Robin Y. McDonald, Division Director, Office of Family Assistance, 370 L'Enfant Promenade SW., 5th Floor East, Washington, DC 20047. Telephone: (202) 401–5587 Email: *robin.mcdonald@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Pilot Project (HHS–2011–ACF–OFA–FO–0196) grants support to organizations that offer community-centered, pre-and post-release responsible fatherhood and supportive services to formerly incarcerated fathers, with the primary purpose of eliminating barriers and supportive services to social and economic self-sufficiency.

Statutory Authority: The award is made under the authority of Claims Resettlement Act of 2010 (Pub. L. 111–291).

Susan Golonka,

Deputy Director, Office of Family Assistance, Administration for Children and Families.

[FR Doc. 2012–25486 Filed 10–16–12; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1056]

Draft Guidance for Industry and Food and Drug Administration Staff; eCopy Program for Medical Device Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''eCopy Program for Medical Device Submissions.'' The purpose of the draft guidance is to explain the new electronic copy (eCopy) program for medical device submissions. The draft guidance describes how FDA plans to implement the eCopy Program under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. This draft guidance is not final nor is it in effect at this time.

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 of 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 November 16, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''eCopy Program for Medical Device Submissions'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to 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. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to CDRH at 301–847–8149. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Phil Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002, 301–796–5678; or Steve Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''eCopy Program for Medical Device Submissions.'' This guidance explains the new eCopy Program for medical device submissions. At this time, submission of an eCopy of a medical device submission is voluntary. However, section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), requires the submission of an eCopy of certain device submissions after issuance of final guidance. This draft guidance describes how FDA plans to implement the eCopy Program under section 745A(b) of the FD&C Act. The inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version.

The eCopy Program is not intended to impact (reduce or increase) the type or amount of data the applicant includes in a submission to support clearance or approval. An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc, digital video disc, or in another electronic media format that FDA has agreed to accept, accompanied by a copy of the signed cover letter and the complete original paper submission.

II. Significance of Guidance

In section 745A(b), Congress granted explicit statutory authorization to FDA to implement the statutory eCopy requirement by providing standards, criteria for waivers, and exemptions in guidance. To the extent that this document provides requirements under section 745A(b)(2)(A) of the FD&C Act (i.e., standards, criteria for waivers, and exemptions), indicated by the use of the words *must* or *required,* this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See 21 CFR 10.115(d).)

However, this document also contains guidance on implementing the eCopy Program. To the extent that this guidance describes recommendations that are not standards, criteria for waivers, or exemptions under section 745A(b)(2), it is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). Such parts of this guidance, when finalized, will represent the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. The use of the word *should* in this guidance means that something is suggested or recommended, but not required. The final guidance will contain both binding and nonbinding provisions.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov* or from the CBER Internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''eCopy Program for Medical Device Submissions,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1797 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120 (510(k)); the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078 (Investigational Device Exemptions); the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231 (Premarket Approval); the collections of information in section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) have been approved under OMB control number 0910–0705 (513(g)); the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control numbers 0910–0332 and 0910–0661 (Humanitarian Use Devices); and the collections of information in section 564 of the FD&C Act (21 U.S.C. 360bbb–3) have been approved under OMB control number 0910–0595 (Emergency Use Authorization). Prior to implementation of this requirement or issuance of a final guidance on this topic FDA will update the existing OMB approved information collections to properly document the submission of information through both paper and electronic means.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments.

Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: October 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–25494 Filed 10–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Oncologic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Oncologic Drugs Advisory Committee Meeting scheduled for November 8, 2012, is canceled. This cancellation applies to both the morning session and afternoon session of the meeting. This meeting was announced in the **Federal Register** of September 20, 2012 (77 FR 58399). The issues for which the FDA was seeking the scientific input of the committee have been resolved.

FOR FURTHER INFORMATION CONTACT: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: October 12, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–25503 Filed 10–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 14, 2012, between approximately 8:30 a.m. and 4 p.m. and on November 15, 2012, between approximately 8:30 a.m. and 2:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at: *https://collaboration.fda.gov/vrbpac.*

Contact Person for More Information: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 14, 2012, the committee will meet in open session to discuss and make recommendations on the safety and immunogenicity of an Influenza A (H5N1) Virus Monovalent Vaccine manufactured by GlaxoSmithKline. On November 15, 2012, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of a Hepatitis B Vaccine manufactured by Dynavax.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 7, 2012. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. on November 14, 2012, and between approximately 12:15 p.m. and 12:45 p.m. on November 15, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 30, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 31, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee