Dated: May 3, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–11819 Filed 5–16–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Subsidized and Transitional Employment Demonstration (STED) and Enhanced Transitional Jobs Demonstration (ETJD).

OMB No.: 0970–0413.

Description: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services (HHS) has launched a national evaluation called the Subsidized and Transitional Employment Demonstration (STED). At the same time, the Employment and Training Administration (ETA) within the Department of labor (DOL) is conducting an evaluation of the Enhanced Transistional Jobs Demonstration (ETJD). These evaluations will inform the Federal government about the effectiveness of subsidized and transitional employment programs in helping vulnerable populations secure unsubsidized jobs in the labor market and achieve self-sufficiency. The projects will evaluate up to twelve subsidized and transitional employment programs nationwide. ACF and ETA are collaborating on the two evaluations. In 2011, ETA awarded grants to seven transitional jobs programs as part of the ETJD, which is testing the effect of combining transitional jobs with enhanced services to assist ex-offenders and noncustodial parents improve labor market outcomes, reduce criminal recidivism and improve family engagement.

The STED and ETJD projects have complementary goals and are focusing on related program models and target populations. Thus, ACF and ETA have agreed to collaborate on the design of data collection instruments to promote consistency across the projects. In addition, two of the seven DOL-funded ETJD programs will be evaluated as part of the STED project. Data for the study will be collected from the following three major sources: Baseline Forms; Follow-Up Surveys (6, 12, and 30 months); and Implementation Research and Site Visits.

The proposed revised information collection includes alternate 6- and 12-month survey instruments which were developed for the STED sites serving young adults. It is being submitted by ACF on behalf of both collaborating agencies.

Respondents: The respondents to the young adult baseline and follow-up surveys include study participants identified as young adults in the treatment and control groups.

Annual Burden Estimates

Note: No additional burden is requested from the already approved information collection.

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Total annual burden hours [1]
6-month survey:				
Youth Respondents (amended version)	533	1	.5	267
Adult Respondents (already approved)	1,334	1	.5	667
12-month survey:				
Youth Respondents (amended version)	533	1	.75	400
Adult Respondents (already approved)	2,667	1	.75	2,000
Total Burden for Surveys				3,334

[1] Rounding may cause slight discrepancies between annual and total estimated burden hours.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV, Attn*: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2013–11762 Filed 5–16–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0501]

Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A; Draft Guidance for Industry and Food and Drug Administration Staff; 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 ''Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A.'' This draft document provides CDRH's proposed interpretation of key provisions of the Federal Food Drug and Cosmetic Act

(FD&C Act), which were added by the FDA Safety and Innovation Act (FDASIA), as those provisions pertain to requests for documentation of rationales for significant decisions and requests for supervisory review of regulatory decisions and actions taken by CDRH. 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 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, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the 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: David S. Buckles, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G470, Silver Spring, MD 20993–0002, 301–796–5447.

I. Background

In July of 2012, section 517A of the FD&C Act (21 U.S.C. 360g–1) was added by section 603 of FDASIA (Pub. L. 112–114). CDRH developed this draft guidance as a companion document to the guidance entitled ''Center for Devices and Radiological Health Appeals Processes,'' (Appeals Guidance) which is also announced in this issue of the **Federal Register**, to provide proposed interpretations of the new law. This document provides interpretations of the terms ''significant decisions'' and ''substantive summary.'' It also addresses who may request documentation of significant decisions under section 517A of the FD&C Act, and how this provision relates to requests under the Freedom of Information Act. When this guidance is finalized, CDRH intends to include the questions and answers in this draft guidance as an appendix to the Appeals Guidance.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on CDRH's appeals processes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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*. To receive ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A'' 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 1821 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to collections of information that 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 the guidance document ''Center for Devices and Radiological Health Appeals Processes'' are approved under OMB control number 0910–0738 (expires April 30, 2016). The draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807 subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 are approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 814 subpart H are approved under OMB control number 0910–0332.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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: May 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11708 Filed 5–16–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0893]

Center for Devices and Radiological Health Appeals Processes; Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Center for Devices and Radiological Health (CDRH) Appeals Processes.'' This document describes the processes available to outside stakeholders to request additional review of decisions or actions by CDRH employees which include requests for supervisory review of an action, petitions, and hearings. Of these, the most commonly used process is the request for supervisory review (a ''10.75 appeal''). This document provides general information about each process as well as guidance on how to submit related requests to CDRH and FDA.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Center for Devices and Radiological Health Appeals Processes''