

Dated: September 30, 2011.
Catherine Ramadei,
Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2011-25853 Filed 10-5-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Personal Responsibility Education Program (PREP) Multi-Component Evaluation—Design Survey.
OMB No.: New collection.

Description: The Family and Youth Services Bureau. (HHS/ACF/ACYF/FYSB) and the Office of Planning, Research, and Evaluation(HHS/ACF/OPRE) in the Administration for Children and Families (ACF) propose a data collection activity as part of the Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

In addition to other activities, the PREP Evaluation will document the design of the PREP State grant programs via data gathered from States and selected sub-awardees funded by PREP. The findings will be of interest to the general public, federal and state policy-makers, PREP sub-awardees, community-based organizations, and other organizations interested in teen pregnancy prevention programming.

The proposed activity involves the collection of information through telephone conversations or in-person interviews held with administrators and program staff at the State and sub-awardee level. The data collection instrument will focus on information related to program context, administration, and design. This includes, but is not limited to: Program goals and strategy/approach, program setting, population characteristics, state-level requirements and processes, program monitoring, and training and technical assistance.

Respondents: State Level Coordinators; Program Directors; Program Staff; General Staff; Schools and Organizations; and Community-Based Organizations.

ANNUAL BURDEN ESTIMATES

Design survey				
Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Discussion Guide for use with State Level Coordinators and State-Level Staff	46	1	1	46
Discussion Guide for use with Program Staff; Schools and Organizations; and Community-Based Organizations	46	1	1	46
Estimated Annual Burden Total for Design Survey				92

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. 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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
 [FR Doc. 2011-25849 Filed 10-5-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0648]

Center for Devices and Radiological Health; Standard Operating Procedures for Network of Experts; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft standard operating procedures (SOPs) for a new "Network of Experts." The draft SOPs describe a new process for staff at the Center for Devices and Radiological Health (CDRH, the center) to gain access to scientific, engineering, and medical expertise when it is needed to supplement existing knowledge and expertise within the Center.

DATES: Submit either electronic or written comments on the report by November 7, 2011.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic

access to the document. Submit electronic comments on the preliminary report 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: Nada O. Hanafi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993-0002, 301-796-5427.

SUPPLEMENTARY INFORMATION:

I. Background

In September 2009, the Task Force on the Utilization of Science in Regulatory Decision Making (Task Force) and the 510(k) Working Group were established to address critical challenges facing the Center and our external constituents. The 510(k) Working Group was charged with evaluating the premarket notification (510(k)) program and exploring actions CDRH can take to enhance our 510(k) decision making. The Task Force was charged with making recommendations on how the Center can quickly incorporate new science—including evolving information, novel technologies, and new scientific methods—into its decision making in as predictable a manner as is practical. The 510(k) Working Group and Task Force made recommendations and then developed a plan of action for implementation of these 510(k) and Science Recommendations. This plan identified internal and administrative matters to be addressed and included an action item of leveraging external expertise.

II. The Draft SOPs

FDA is announcing the availability of two draft SOPs, one entitled, “Network of Experts—Expert Utilization Standard Operating Procedure” and one entitled, “Network of Experts—Expert Enrollment Standard Operating Procedure.” The purpose of the draft SOPs is to develop a network of external experts to appropriately and efficiently leverage external scientific expertise, and to describe the process for staff engagement with external experts. The network will be built on a series of agreements with external organizations including professional, scientific, and medical organizations and academic institutions. The draft SOPs describe CDRH processes for providing CDRH staff with access to scientific, engineering, and medical expertise

when it is needed to supplement existing knowledge and expertise within CDRH. The network of experts is designed to broaden CDRH’s exposure to scientific viewpoints, but not to provide external policy advice or opinions.

CDRH has a knowledgeable, professional internal cadre of scientific expertise, including over 800 scientists, engineers, and clinicians. Despite this internal resource, it is unrealistic to expect CDRH staff to encompass all of the applicable expertise and experience necessary to fulfill our mission given the rapidly growing variety and complexity of medical devices. This is particularly true when it comes to new and emerging fields of science and pioneering technologies. In these areas, it is often necessary for our experts to gain further scientific understanding from external sources. The Network of Experts will facilitate this exchange.

In developing the draft SOPs, CDRH assessed best practices. CDRH is also beginning a pilot project to use these draft SOPs on a trial basis. Experience from the pilot, along with comments on this notice, will further assist the agency in determining whether the draft SOPs should be improved going forward.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons interested in obtaining a copy of the draft SOPs may do so by using the Internet. The draft SOP entitled: “Network of Experts—Expert Utilization Standard Operating Procedure” can be obtained from FDA’s Web site at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm271521.htm>. The draft SOP entitled: “Network of Experts—Expert Enrollment Standard Operating Procedure” can be obtained from FDA’s Web Site at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm271523.htm>. The draft SOPs are also available from <http://www.regulations.gov> and can be located using the docket number found in brackets in the heading of this document.

Dated: September 29, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011-25597 Filed 10-5-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0721]

Guidance for Industry on Implementation of the Fee Provisions of the FDA Food Safety Modernization Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act.” FDA is issuing this guidance to provide answers to common questions that might arise about the new fee provisions and FDA’s plans for their implementation in fiscal year (FY) 2012.

DATES: Submit either electronic or written comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Regulatory Affairs, Office of Resource Management, 12420 Parklawn Dr., Rm. 2012, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Amy Waltrip, Office of Regulatory Affairs, Office of Resource Management, 12420 Parklawn Dr., Rm. 2012, Rockville, MD 20857, 301-796-8811.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act.” The purpose of the guidance document is to provide