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]

BILLING CODE 4160–01–P

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

guidance to industry on the implementation of the fee provisions of section 107 of the FDA Food Safety Modernization Act of 2011 (FSMA) (Pub. L. 111–353). Section 107 of FSMA amended section 743 of the Federal Food, Drug, and Cosmetic Act to provide FDA with the authority to collect fees related to food. In the **Federal Register** of August 1, 2011 (76 FR 45820), FDA published a notice establishing fee rates for FY 2012 for domestic and foreign facility reinspections, recall orders, and importer reinspections. On October 1, 2011, FDA will begin implementation of the fee provisions of section 107 of FSMA. The guidance document is intended to provide answers to common questions that might arise about the new fee provisions and FDA's plans for their implementation in FY 2012.

This guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the fee provisions of FSMA are currently being implemented, and guidance is needed to help effectuate the implementation. The guidance provides information necessary for affected persons to understand the implementation of these FSMA fee provisions. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

The guidance represents the Agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the guidance 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.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: September 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25831 Filed 10–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number: OIG–1204–N]

Proposed Revision of Performance Standards for State Medicaid Fraud Control Units

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and opportunity for comment.

SUMMARY: This notice seeks comment on an OIG proposal to revise standards for assessing the performance of the State Medicaid Fraud Control Units (MFCUs or Units). This proposal would replace and supersede standards published on September 26, 1994 (59 FR 49080).

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on December 5, 2011.

ADDRESSES: In commenting, please refer to the file code OIG–1204–N. Because of staff and resource limitations, OIG cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at *http://www.regulations.gov.*

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Office of Congressional and Regulatory Affairs, Department of Health & Human Services, Attention: OIG–118–N, Room 5541, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Office of Inspector General, Department of Health & Human Services, Cohen Building, Room 5541, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–1343.

We do not accept comments by FAX transmission. All submissions received must include the agency name and docket number for this **Federal Register** document. All comments, including attachments and other supporting materials received, are subject to public disclosure.

FOR FURTHER INFORMATION CONTACT:

Richard B. Stern, OIG Office of Evaluation and Inspections, (202) 619–0480.

Patrice S. Drew, Office of External Affairs, (202) 619–1368.

SUPPLEMENTARY INFORMATION:

I. Background

The mission of the MFCUs, as established in Federal statute, is to investigate and prosecute Medicaid provider fraud and patient abuse and neglect. The States are responsible for operation of the MFCUs and receive reimbursement for a percentage of their costs from the Federal Government. Under section 1903(a)(6) of the Social Security Act (Act), States are reimbursed for 90 percent of their costs for the first 3 years of an MFCU's operation and 75 percent for subsequent years. All MFCUs are currently reimbursed at 75 percent of the costs of operating a certified MFCU.

OIG is delegated authority under 1903(q) and 1903(a)(6) of the Act to certify and annually recertify Units as eligible for Federal Financial Participation (FFP), and to reimburse States for costs incurred in operating an MFCU. Through the certification and recertification process, OIG ensures that the Units meet the requirements for FFP set forth in section 1903(q) of the Act and in OIG regulations found at 42 CFR part 1007. The performance standards set forth in this guidance document constitute the standards that OIG will apply in determining the effectiveness of State Units in carrying out MFCU required functions. As part of the recertification process, OIG reviews