Cosmetic Act to include several new significant provisions. MDUFMA authorizes the following provisions: (1) User fees for certain premarket applications, (2) establishment inspections by FDA-accredited persons (third-parties), and (3) new requirements for reprocessed single-use devices. In addition, the new law contains several provisions that, while narrower in scope than the previously mentioned provisions, are significant changes to the device law. These include a modular review program for premarket approval applications (PMAs), electronic labeling for certain prescription devices, several provisions concerning devices for pediatric use, and a new labeling requirement that requires the manufacturer's name to appear on the device itself, with certain exceptions.

The agency has been working to implement the new law since its passage in October 2002. During this time, FDA has accomplished the following milestones: Established a user fee program with payment, billing, and appeals procedures; met statutory timeframes for the release of the accreditation criteria for persons conducting third-party inspections and the identification of certain reprocessed single-use devices that will be subject to additional premarket requirements; and published several guidances, such as those related to PMA supplement definitions and bundling of multiple devices in a single application. The agency is drafting other documents to be issued in the near future.

Agenda: On December 3, 2003, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. The agenda will consist of the following panel sessions that will include panelists from FDA, industry, and other stakeholders:

- Panel 1: How is the User Fees Process Working? This panel will consider the small business determinations and the user fee process and performance goals.
- Panel 2: Electronic Labeling and Identification of the Manufacturer on the Device. This panel will address electronic labeling for prescription devices intended for use in healthcare facilities (section 206 of MUDFMA (Public Law 107–250)) and identification of the manufacturer on the device itself (section 301 of MDUFMA (Public Law 107–250)).
- Panel 3: Bundling, Modular PMA, and Expedited PMAs. This panel will discuss guidances that address various PMA issues, including definitions of supplements, modular review, bundling multiple devices/indications for use in a single application, and clinical studies of pediatric devices.
- Panel 4: Third-Party Inspection Program. This panel will discuss implementation of the program, including eligibility criteria for use of a third party by a manufacturer.
- Panel 5: Reuse. This panel will discuss FDA-identified reprocessed single-use devices that will require premarket submission of validation data and the associated guidance for submission of data.
- General Discussion Period From the Floor: At the conclusion of the panels, there will be a general discussion from the floor.

Also at this time, FDA is particularly interested in receiving comments from stakeholders on other topics for discussion. The agency is interested in receiving recommendations about other provisions yet to be implemented both in terms of their priority for implementation and specifics on the implementation itself.

FDA will place an additional copy of any material it receives on the docket for this document (2003N–0422). Comments and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

Registration: Online registration for the meeting is required by November 3, 2003. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/120303.html* by November 3, 2003. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–2845 by November 3, 2003.

If you need special accommodations due to a disability, please contact Sherrie Appel at 301–443–2845 at least 7 days in advance.

Transcripts: Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 22, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–24494 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cooperative Agreement to the Fund for the City of New York, on Behalf of the New York City Department of Health and Mental Hygiene and the Fund for Public Health in New York, Inc.

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Notice of award.

Catalog of Federal Domestic Assistance: #93.003.

SUMMARY: Notice is hereby given that a noncompetitive cooperative agreement award is being made to the Fund for the City of New York, on behalf of the New York City Department of Health and Mental Hygiene and the Fund for Public Health in New York, Inc. The award is being made to support the efforts of the New York City Department of Health and Mental Hygiene to develop model approaches for addressing the special needs of high density metropolitan areas with high levels of risk for bioterrrorism attacks and other public health emergencies.

This eighteen month agreement at a level of $5 million is being funded non-competitively because it is expected to provide useful information and guidance to this Department and to other health departments and levels of government regarding how to deal with threats and actual events in high density areas at high risk for attacks. One area of particular interest is developing and evaluating best practice guidelines for emergency preparedness in primary care settings. This includes developing effective models of clinic training. There has been concern expressed that the Federally Qualified Health Centers have not been sufficiently involved in regional planning for, and preparing to respond to, a bioterrorist event or other public health emergency. These clinics will likely serve a role with regard to triaging victims, as well as potentially offering mass prophylaxis. This effort will be designed to develop best practice guidelines and recommendations for primary care emergency management; develop an educational curriculum to disseminate best emergency practices to primary care centers; and test, evaluate and refine the guidelines, training curriculum, and template drills to share with primary care centers citywide.

A second area of interest is preparation of terrorism preparedness exercises. It is important to identify

operational strengths and opportunities for improvement through simulated exercises. Practical exercises or drills should both reinforce knowledge and uncover opportunities for improvement in written disaster plans. Biological disaster exercises should be of sufficient intensity to challenge the management and response operations during the exercise, in a way similar to what would be expected during an actual biological terrorist event. The goal is to develop and disseminate a group of hospital-based, validated, Web-accessible bioterrorism preparedness tabletop exercises.

Because of its population density, experience with previous terrorist attacks, and subsequent efforts to build a response capacity, New York City is uniquely qualified to demonstrate model approaches that would inform regional or national preparedness efforts. A strong evaluation focus is built into the entire project to ensure that products are produced which will allow other metropolitan areas to replicate successful elements of the project.

Authority: This award will be made pursuant to section 241 (Evaluation of Programs) of the Public Health Service Act as well as section 319C of the Public Health Service Act (Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies), CFDA#93.003.

FOR FURTHER INFORMATION CONTACT: Michael Millman, Director, Division of Information and Analysis, Office of Planning and Evaluation, Health Resources and Services Administration, Parklawn Building, Room 14–45, 5600 Fishers Lane, Rockville, MD 20857, Phone 301–443–0368.

Dated: August 14, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–24489 Filed 9–26–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Grant Awards

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Announcement of grant awards.

SUMMARY: The Office of Rural Health Policy (ORHP), HRSA is awarding the following grants to the States, as authorized. Section 1820 of the Social Security Act authorized the Medicare Rural Hospital Flexibility Program (MRHFP). Reauthorization is pending. The appropriation for this program is provided in Public Law 108–7 (Consolidated Appropriations Resolution, 2003). The purpose of this notice is to announce the grant awards. The grant year began on September 1, 2003.

Medicare Rural Hospital Flexibility Program Awards (CFDA# 93.241). These grants allow each State to designate a focal point of contact for this program. The MRHFP helps sustain the rural healthcare infrastructure, with the Critical Access Hospital (CAH) as the hub of an organized system of care (in those communities where they exist), through the mechanisms of the Flex program. These mechanisms include the State Rural Health Plan (SRHP), CAHs, networks, Quality Improvement and EMS integration initiatives. Additionally, MRHFP must foster the growth of collaborative rural delivery systems across the continuum of care at the community level with appropriate external relationships for referral and support.

The following grantees have received awards for the first year of a 5-year project period.

- AL—Alabama Department of Public Health, $480,000
- AK—State of Alaska Department of Health & Social Services, $544,000
- AZ—University of Arizona, $573,000
- AR—Arkansas Department of Health, $421,000
- CA—California State Department of Public Health, Department of Health Services, $326,200
- CO—Colorado Rural Health Center, $529,200
- FL—Florida Department of Health, $550,000
- GA—Georgia Department of Community Health, $585,000
- HI—Hawaii State Department of Health, $543,000
- ID—Idaho State Department of Health & Welfare, $474,890
- IL—Illinois Department of Public Health, $668,000
- IN—Indiana State Department of Health, $526,000
- IA—Iowa Department of Public Health, $465,000
- KS—Kansas State Department of Health and Environment, $620,000
- KY—University of Kentucky, Research Foundation, $583,800
- LA—Louisiana Department of Health and Hospitals, $385,000
- ME—Maine Department of Human Services, $435,000
- MA—Massachusetts Department of Public Health, $223,340
- MI—Michigan Department of Community Health, $513,600
- MN—Minnesota Department of Health, $685,000
- MS—Mississippi State Department of Health, $395,000
- MO—Missouri Department of Health, $407,750
- MT—Montana Department of Public Health and Human Services, $660,000
- NE—State of Nebraska, $630,000
- NV—University of Nevada, Reno, $578,000
- NH—State of New Hampshire, $365,500
- NM—State of New Mexico, $231,580
- NY—Health Research, Inc., New York, $421,250
- NC—North Carolina Department of Health and Human Services, $574,000
- ND—University of North Dakota, $655,000
- OH—State of Ohio—Department of Health, $600,000
- OK—Oklahoma State University, Center for Health Sciences, $614,000
- OR—Oregon Health & Sciences University, $653,850
- PA—Pennsylvania State Department of Public Health & Human Services, $357,390
- SC—South Carolina State Office of Rural Health, Inc., $452,560
- SD—South Dakota State Department of Health, $660,000
- TN—Tennessee State Department of Health, $517,000
- TX—Office of Rural Community Affairs, Texas, $615,000
- UT—Utah Department of Health, $371,000
- VT—Vermont State Department of Health, $234,250
- VA—Virginia State Department of Health, $352,000
- WA—Washington State Department of Health, $585,000
- WV—West Virginia Department of Health & Human Resources, $485,700
- WI—University of Wisconsin—Madison, $651,145
- WY—Wyoming State Department of Health, $379,300

FOR FURTHER INFORMATION CONTACT: Contact Forest Calico, Project Officer, Medicare Rural Hospital Flexibility Program, Office of Rural Health Policy, HRSA, 5600 Fishers Lane, Room 9A–55, Rockville, MD 20857, (301) 443–0835.

Dated: September 17, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–24490 Filed 9–26–03; 8:45 am]

BILLING CODE 4165–15–P