

resources it will mobilize, how those resources will directly benefit the project, and how the project will ultimately benefit low-income individuals and families.

(3) If the application proposes a project with a training and technical assistance focus, the application indicates the number of organizations and/or staff that will benefit from those services.

(4) If the application proposes a project with data collection focus, the application describes the mechanism it will use to collect data, how it can assure collections from a significant number of States, and the number of States willing to submit data to the applicant.

(5) If the application proposes to develop a symposium series or other policy-related project(s), the application identifies the number and types of beneficiaries.

(6) The application describes methods of securing participant feedback and evaluations of activities.

#### Criterion V: Budget and Budget Justification (Maximum: 5 Points)

##### Factors:

(1) The resources requested are reasonable and adequate to accomplish the project.

(2) Total costs are reasonable and consistent with anticipated results.

#### 2. Review and Selection Process

##### Initial OCS Screening

Each application submitted to OCS will be screened to determine whether it was received by the closing date and time.

Applications received by the closing date and time will be screened for completeness and conformity with the following requirements. Only complete applications that meet the requirements listed below will be reviewed and evaluated competitively. Other applications will be returned to the applicants with a notation that they were unacceptable and will not be reviewed.

All applications must comply with the following requirements except as noted:

##### OCS Evaluation of Applications

Applications that pass the initial OCS screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this program announcement.

The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success.

The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application. The review panel awards points only to applications that are responsive to the program elements and relevant review criteria within the context of this program announcement.

The OCS Director and program staff use the reviewer scores when considering competing applications. Reviewer scores will weigh heavily in funding decisions, but will not be the only factors considered.

Applications generally will be considered in order of the average scores assigned by the review panel. Because other important factors are taken into consideration, highly ranked applications are not guaranteed funding. These other considerations include, for example: The timely and proper completion by the applicant of projects funded with OCS funds granted in the last five (5) years; comments of reviewers and government officials; staff evaluation and input; amount and duration of the grant requested and the proposed project's consistency and harmony with OCS goals and policy; geographic distribution of applications; previous program performance of applicants; compliance with grant terms under previous HHS grants, including the actual dedication to program of mobilized resources as set forth in project applications; audit reports; investigative reports; and applicant's progress in resolving any final audit disallowance on previous OCS or other Federal agency grants.

#### VI. Award Administration Information

##### 1. Award Notices

Following approval of the application selected for funding, ACF will mail a written notice of project approval and authority to draw down project funds. The official award document is the Financial Assistance Award that specifies the amount of Federal funds approved for use in the project, the project and budget period for which support is provided and the terms and conditions of the award. The Financial Assistance Award is signed and issued via postal mail by an authorized Grants Officer.

ACF will notify unsuccessful applicants after the award is issued to the successful applicant.

##### 2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental).

##### 3. Special Terms and Conditions of Awards

None.

##### 4. Reporting Requirements

All grantees are required to submit semi-annual program reports and semi-annual expenditure reports (SF-269) with final reports due 90 days after the project end date. A suggested format for the program report will be sent to all grantees after the awards are made.

#### VII. Agency Contacts

**Program Office Contact:** Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-mail: [OCS@lcnnet.com](mailto:OCS@lcnnet.com), Phone: 1-800-281-9519.

**Grants Management Office Contact:** Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-mail: [OCS@lcnnet.com](mailto:OCS@lcnnet.com), Phone: 1-800-281-9519.

#### VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: <http://www.acf.hhs.gov/programs/ocs>.

Dated: April 27, 2004.

**Clarence H. Carter,**

*Director, Office of Community Services.*

[FR Doc. 04-10088 Filed 5-5-04; 8:45 am]

BILLING CODE 4184-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 2003N-0565]

##### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Food and Drug Administration Rapid Response Surveys

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 7, 2004.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Generic Food and Drug Administration Rapid Response Surveys—(OMB Control Number 0910-0500—Extension)**

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made

available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section 519 of the act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA, to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314)

and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910-0291) and the vaccine adverse event reporting system. FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to obtain quickly vital information about medical product risks and interventions to reduce risks so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

In the **Federal Register** of January 7, 2004 (69 FR 923), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 200                | 30 (maximum)                  | 6,000                  | 0.5                | 3,000       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA projects 30 emergency risk-related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only 1 time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the

requested information and fill in the answers.

Dated: April 29, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-10267 Filed 5-5-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Cooperative Agreement to Support the Illinois Institute of Technology's National Center for Food Safety and Technology; Notice of Intent to Accept and Consider a Single Source Application; Availability of Funds for Fiscal Year 2004**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing its intent to accept and consider a single source application for