Approved but Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

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).

Direct Federal grants, sub-award funds, or contracts under this ACF program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the Equal Treatment For Faith-Based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR 87.1 or the HHS Web site at: *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

3. Reporting Requirements

Grantees will be required to submit program progress and financial reports (SF–269 found at *http://www.acf.hhs.gov/programs/ofs/forms.htm*) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. Final programmatic and financial reports are due 90 days after the close of the project period.

Program Progress Reports: Semi-Annually.

Financial Reports: Semi-Annually.

VII. Agency Contacts

Program Office Contact: William D. Riley, Director, Family Violence Division, 330 C Street, SW., Switzer Building, Room 2117, Washington, DC 20447. Phone: 202–104–5529. E-mail: *wriley@acf.hhs.gov.*

Grants Management Office Contact: Peter Thompson, Grants Officer, Administration on Children, Youth and Families, 330 C Street, SW., Switzer Building, SW., Washington, DC 20447. Phone: 202–401–4608. E-mail: *pathompson@acf.hhs.gov.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005, applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Please reference Section IV.3 for details about acknowledgement of received applications.

Dated: July 15, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth & Families.

[FR Doc. 05–14459 Filed 7–21–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of the Committee: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 9, 2005, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Scott A. Colburn, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–6892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will discuss and make recommendations on methods to assess the potential of disease transmission by multiple-use nozzle jet injectors (i.e., jet injectors for which the fluid path for the injection is used more than once). The discussion will include premarket testing recommendations to address this issue.

Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 3, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of deliberations and for approximately 30 minutes near the end of deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 3, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–0450, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory committee Act (5 U.S.C. app. 2).

Dated: July 18, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–14455 Filed 7–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0492] (formerly Docket No. 02D–0492)

Guidance for Industry on Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers; 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 ''Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' This guidance provides a description and basis for a process by which to select a maximum recommended starting dose (MRSD) for a first-in-human clinical trial of a therapeutic in adult healthy volunteers.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lois M. Freed, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2647.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' This guidance provides a description and basis for a process by which to select an MRSD for a first-in-human clinical trial of a new molecular entity in adult healthy volunteers. In the **Federal Register** of January 16, 2003 (68 FR 2340), FDA published a notice making available a draft guidance entitled ''Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' The notice gave interested persons an opportunity to submit comments. As a result of the comments, certain sections of this guidance were reworded to improve clarity. The guidance outlines a recommended standardized approach (including common conversion factors for calculating human equivalent doses) and vocabulary for selecting an MRSD based on animal data, and discusses factors to be considered in determining reasonable safety margins. This approach is applicable to a first-in-human trial of a new drug or biological therapeutic, regardless of intended clinical use. The guidance also discusses alternative approaches and provides some examples of circumstances under which alternative approaches for selection of an MRSD should be considered. Dose escalation is not addressed.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on estimating the maximum safe starting dose in initial clinical trials for therapeutics in adult healthy volunteers. 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**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination 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 document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14456 Filed 7–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Health Service Corps Uniform Data System (OMB No. 0915–0232): Revision

The National Health Service Corps (NHSC) of the Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The NHSC needs to collect data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The following information will be collected from each site: services offered and delivery method; users by various characteristics; staffing and utilization; charges and