approximately $140,000 for the first year. An additional 2 years of support will be available, depending upon fiscal year appropriations, and successful performance.

VI. Reasons for Single-Source Selection

Competition is limited to WHO/IPCS because it is the parent organization of JECFA, which provides scientific advice to the Codex Alimentarius Commission. The international food standards established by the Codex Alimentarius Commission are recognized by WTO as necessary to protect public health and presumed to be consistent with the Sanitary and Phytosanitary Agreement of GATT. These programs under IPCS are the only such programs in existence and make IPCS unique as a participant in international standard setting for food ingredients, contaminants, and veterinary drug residues. Awarding this cooperative agreement will ensure that the risk assessments provided by JECFA to the Codex Alimentarius Commission are science-based, ensure that food sold in the United States is safe, and enhance the safe use of food additives in imported food.

VII. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (rev. 5/01) with copies of the appendices for each of the copies, should be submitted to Rosemary Springer (see **ADDRESSES**). The outside of the mailing package should be labeled ''Response to RFA-FDA-CFSAN-02-2''. The application will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before May 1, 2002. Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the Public Health Service (PHS) to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

VIII. Reporting Requirements

An annual financial status report (FSR) (SF–269) is required. The original and two copies of the report must be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the grant. Failure to file FSR in a timely fashion will be grounds for suspension or termination of the grant.

An annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report.

A final program progress report, FSR (SF–269), and invention statement must be submitted within 90 days after the expiration of the project period as noted on the notice of grant award.

IX. Review Procedures and Evaluation Criteria

A. Review Procedures

The application submitted by WHO/IPCS will first be reviewed by grants management and program staff for responsiveness. The requested budget must not exceed $140,000 (direct and indirect costs). The application will be considered nonresponsive if it is not in compliance with this document. If an application is found to be nonresponsive, it will be returned to the applicant without further consideration.

The application submitted by IPCS will undergo noncompetitive dual peer review. The application will be reviewed for scientific and technical merit by an ad hoc panel of experts based upon the applicable evaluation criteria. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence.

B. Review Criteria

The application will be reviewed and evaluated according to the following criteria:

1. The application clearly demonstrates an understanding of the purpose and objectives of the cooperative agreement regarding the safety of food ingredients, contaminants, and veterinary drug residues.

2. The application clearly describes the steps and a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the cooperative agreement. The application presents a clear plan and schedule of steps to accomplish the goals of the cooperative agreement.

3. The application establishes the applicant's ability to perform the responsibilities under the cooperative agreement including the availability of appropriate staff and sufficient funding.

4. The application specifies the manner in which interaction with FDA will be maintained throughout the lifetime of the project.

5. The application specifies how IPCS will monitor progress of the work under the cooperative agreement and how progress will be reported to FDA.

6. The application shall include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, equipment, and supplies; and (2) the sources of funds to meet those needs.

X. Mechanism of Support

Support for this project will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant programs of PHS, including provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and PHS's grants policy statement. The regulations issued under Executive Order 12372 do not apply. The length of support will be 1 year with the possibility of an additional 2 years of noncompetitive support. Continuation beyond the first year will be based upon satisfactory performance during the preceding year and the availability of Federal fiscal year appropriations. The NIH modular grant program does not apply to this FDA program.

XI. Legend

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc. by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: March 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7819 Filed 3–27–02; 2:54 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology 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 Committee: Obstetrics and Gynecology 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 April 22, 2002, from 8 a.m. to 5 p.m.

Location: Gaithersburg Marriott Washingtonian Center, Salons E, F, and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Joyce M. Whang, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an intrapartum fetal monitor. Background information, 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. Material for the April 22, 2002, meeting will be posted on April 19, 2002.

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 April 11, 2002. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 11, 2002, 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 301–594–1283, 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: March 25, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–7731 Filed 3–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Meeting of the Nonprescription Drugs Advisory Committee With Consultation From the Pulmonary and Allergy Drugs Advisory Committee and the Dermatologic and Ophthalmologic Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Nonprescription Drugs 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 April 22, 2002, from 8 a.m. to 5 p.m. and on April 23, 2002, from 9 a.m. to 12 noon.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 22, 2002, the committee will consider the safety and efficacy of new drug applications (NDA): NDA 19–658, CLARITIN Tablet; NDA 20–704, CLARITIN RediTab; and NDA 20–641, CLARITIN Syrup. These three CLARITIN products (loratadine, Schering-Plough Corp.) are immediate release formulations of the products that are proposed for over-the-counter (OTC) use for the relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria (CIU). The primary purpose of the meeting is to discuss CIU as an OTC indication. The background material for this meeting will be posted under the Nonprescription Drugs Advisory Committee (NDAC) Docket site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2002 and scroll down to NDAC.)

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 April 12, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 22, 2002, and the meeting will be closed to the public between approximately 9 a.m. and 12 noon on April 23, 2002. Time allotted for each presentation may be limited. Priority for presentations will be given to those who demonstrate that they plan to address CIU as an OTC indication. Those desiring to make formal oral presentations should notify the contact person before April 12, 2002, 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 Sandra Titus at least 7 days in advance of the meeting.

Closed Committee Deliberations: On April 23, 2002, from approximately 9 a.m. to 12 noon, the meeting will be closed to provide an annual update and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: March 25, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–7730 Filed 3–29–02; 8:45 am]

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