b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Measures of effectiveness.

f. Additional requested information, including (1) data related to performance target goals; (2) data on progress toward achieving objectives; (3) an inventory of total individual capacity building assistance and proactive training for the reporting period; and (4) data related to the quality assurance system.

2. Second trimester interim progress report shall be due 30 days after the completion of the first eight (8) months of the project period. This second trimester progress report will serve as your non-competing continuation application for the next funding cycle. (See Continuing Application Requirements provided by Procurement and Grants Office.) This report must include elements a–f, as listed in the first trimester report, and be completed during this time period (months 5–8). The report should also include the following:

a. Base line and actual level of core performance indicators.

b. Specific guidance, which will be provided by the CDC three months prior to the due date.

3. The third trimester progress report shall be due 30 days after the end of the budget period. This report must include elements a–f as listed in the first trimester report, elements a–b as listed in the second trimester report, and completed during this time period (months 9–12).

4. Financial status report is due no more than 90 days after the end of the budget period.

5. Final financial and performance reports are due no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement.

For Pre-application Technical Consultation: Send questions regarding this application to *DHAPCBAPT@CDC.GOV*. You will receive a response within 24–48 hours.

For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2700.

For program technical assistance, contact: Gerlinda Gallegos Somerville, Public Health Analyst, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention, Capacity Building Branch, 1600 Clifton Road, Mailstop E–40, Atlanta, GA 30333, Telephone: 404–639–2918. E-mail address: *DHAPCBAPT@CDC.GOV.*

For financial, grants management, or budget assistance, contact: Roslyn Curington, Grants Management Specialist, Centers for Disease Control and Prevention, Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146. Telephone: 770–488–2767, E-mail address: *zlp8@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: April 6, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–7286 Filed 4–11–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5033–N6]

Medicare Program; Cancellation of the April 13, 2005 Advisory Board Meeting on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Cancellation of meeting.

SUMMARY: This notice cancels the April 13, 2005 Advisory Board Meeting on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. We published the meeting notice in the **Federal Register** on March 25, 2005 (70 FR 15343).

DATES: *Effective Date:* The notice announcing the cancellation of the meeting is effective April 12, 2005.

FOR FURTHER INFORMATION CONTACT: Pamela Kelly by e-mail at *ESRDAdvisoryBoard@cms.hhs.gov* or telephone at (410) 786–2461.

SUPPLEMENTARY INFORMATION: On June 2, 2004, we published a **Federal Register** notice requesting nominations for individuals to serve on the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for End-Stage Renal Disease (ESRD) Services. The June 2, 2004 notice also announced the establishment of the Advisory Board and the signing by the Secretary on May 11, 2004 of the charter establishing the Advisory Board. On January 28, 2005, we published a **Federal Register** notice (70 FR 4132) announcing the appointment of eleven individuals to serve as members of the Advisory Board on the Demonstration of a Bundled Case-Mix Adjusted Payment System for ESRD Services, including one individual to serve as co-chairperson, and one additional co-chairperson, who is employed by CMS. The first public meeting of the Advisory Board was held on February 16, 2005. The second public meeting of the Advisory Board scheduled for April 13, 2005 has been cancelled.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 7, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–7408 Filed 4–8–05; 1:51 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the World Health Organization International Programme on Chemical Safety

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing its intent to accept and consider a single source application for the award of a cooperative agreement to the World Health Organization (WHO) to support the International Programme on Chemical Safety (IPCS). FDA anticipates providing $90,000 (direct and indirect costs) in fiscal year 2005 in support of this project. Subject to the availability of Federal funds and successful performance, 2 additional years of support up to $90,000 per year (direct and indirect costs) will be available. FDA will support the research

covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The cooperative agreement ensures FDA's participation and leadership in important international risk assessment and standard setting activities for food ingredients, contaminants, and veterinary drug residues. The development of such international standards provides the public with greater assurance of the quality and safety of food sold in the United States.

II. Eligibility Information

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

As of October 1, 2003, applicants are required to have a Dun and Bradstreet Number (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, foreign applicants should go to *http://www.grants.gov/RequestaDUNS*, 4th paragraph. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

III. Application and Submission

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.gov* or *cpolit@oc.fda.gov*. This RFA can also be viewed on *Grants.gov* under ''Grant Find.'' A copy of the complete RFA can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at *http://www.cfsan.fda.gov/list.html*.

Dated: April 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7288 Filed 4–11–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0182]

Guidance for Industry and Food and Drug Administration Staff; Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product; 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 and FDA staff entitled ''Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product.'' The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) delegates to the Office of Combination Products (OCP) responsibility for resolving disputes about the timeliness of premarket review of combination products. This guidance document provides information about presenting requests for resolution of disputes about the timeliness of premarket review of combination products.

DATES: Submit written or electronic comments on agency guidances at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance document to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments concerning 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: Suzanne O'Shea, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934, FAX: 301–427–1935.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product.'' In the **Federal Register** of May 4, 2004 (69 FR 24653), FDA issued a notice of availability of a draft guidance document covering the same topic. The draft guidance document was entitled ''Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance.''

MDUFMA delegated to OCP responsibility for resolving disputes about the timeliness of reviews of premarket applications covering combination products. This guidance document provides information on how an applicant submitting an application covering a combination product can submit a request that OCP resolve such a dispute.

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 how to present to OCP disputes pertaining to the timeliness of reviews of combination products. 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 statute 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 two paper copies of any mailed comments, except that individuals may