DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02005]

Sexually Transmitted Disease Faculty Expansion Program; Notice of Availability of Funds; Amendment

A notice announcing the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for a Sexually Transmitted Disease (STD) Faculty Expansion Program (FEP)was published in the **Federal Register** on August 23, 2001, [Vol. 66, No. 164, Pages 44351–44354]. The notice is amended as follows:

(1) On page 44351, third column, at the beginning of sixth paragraph, under Section C. Availability of Funds, insert a sentence, ''Applicants may incur pre-award costs up to 90 days prior to the award, however, all pre-award costs are incurred at the applicants' risk.'' before the paragraph beginning ''CDC is * * * the Use of Funds section.''

(2) On page 44352 and third column, the section title ''E. Application Content'' should be replaced with ''E. Content'' and a word, ''Application'' should be inserted as a subtitle above the beginning of the last paragraph, ''The narrative should be * * * in the order presented below:''

Dated: August 31, 2001.

John L. Williams,

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

[FR Doc. 01–22503 Filed 9–6–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guideline for Prevention of Intravascular Catheter-Related Infections

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice of availability and request for public comment.

SUMMARY: This notice is a request for review of and comment on the *Draft Guideline for Prevention of Intravascular Catheter-Related Infections,* available on the CDC website at *www.cdc.gov/ncidod/hip/ivguide.htm.* The guideline has been developed for practitioners who insert and maintain intravascular catheters and for personnel who are responsible for monitoring and preventing infections in healthcare settings. The guideline is intended to replace the *Guideline for Prevention of Intravascular Device-Related Infections* published in 1996.

DATES: Comments on the *Draft Guideline for Prevention of Intravascular Catheter-Related Infections* must be received in writing on or before October 22, 2001.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the *Draft Guideline for Prevention of Intravascular Catheter-Related Infections* should be submitted to the Resource Center, Attention: IVGuide, Division of Healthcare Quality Promotion, CDC, Mailstop E–68, 1600 Clifton Rd., NE, Atlanta, Georgia 30333; fax 404 498–1244; e-mail: *ivrequests@cdc.gov;* or Internet: *www.cdc.gov/ncidod/hip/ivguide.htm.*

ADDRESSES: Comments on the *Draft Guideline for Prevention of Intravascular Catheter-Related Infections* should be submitted to the Resource Center, Attention: IVGuide, Division of Healthcare Quality Promotion, CDC, Mailstop E–68, 1600 Clifton Road, NE, Atlanta, Georgia 30333; fax 404–498–1244; e-mail: *ivcomments@cdc.gov;* or Internet: *www.cdc.gov/ncidod/hip/ivguide.htm.*

SUPPLEMENTARY INFORMATION: The *Draft Guideline for Prevention of Intravascular Catheter-Related Infections* is designed to provide healthcare practitioners with background information and specific recommendations to reduce the incidence of intravascular catheter-related bloodstream infections: Part I: Intravascular Catheter-Related Infections: An Overview reviews pivotal issues and controversies in intravascular catheter use and maintenance. These issues include definitions and diagnosis of catheter-related infection, barrier precautions during catheter insertion, skin antisepsis, intervals for replacement of catheters and intravenous fluids and administration sets, catheter site case, the role of specialized intravascular catheter personnel and the use of antimicrobial/antiseptic impregnated catheters, prophylactic systemic antibiotics, flush solutions, and anticoagulants. Part II: Recommendations for Prevention of Intravascular Catheter-Related Infections provides consensus recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and other professional societies. Most recommendations are pertinent for the inpatient, outpatient, and home care setting, unless otherwise noted.

HICPAC was established in 1991 to provide advice and guidance to the Secretary and the Assistant Secretary for Health, DHHS; the Director, CDC; and the Director, National Center for Infectious Diseases, regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections in U.S. healthcare facilities. The committee advises CDC on guidelines and other policy statements regarding prevention of healthcare-associated infections and related adverse events.

Dated: August 31, 2001.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 01–22502 Filed 9–6–01; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0370]

Preparation for ICH Meetings in Brussels, Belgium, Including Progress on Implementing of the Common Technical Document; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration is announcing a public meeting entitled ''Preparation for ICH Meetings in Brussels, Belgium, Including Progress on Implementation of the Common Technical Document'' to solicit information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Brussels, Belgium. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Brussels, Belgium, October 22 to 25, 2001, at which discussion of the Common Technical Document and other topics related to the upcoming meeting in Brussels, Belgium will take place.

Date and Time: The public meeting will be held on October 5, 2001, from 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD–

21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, e-mail: Topper@cder.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations to the contact person by September 28, 2001.

If you need special accommodations due to a disability, please contact Kimberly Topper (address above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 12:30 and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by September 28, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on September 28, 2001, under Docket No. 01N–0370, at the Docket Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: August 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–22471 Filed 9–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94P–0240]

Small Entity Compliance Guide: ''Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, Pectin;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of March 16, 1999 (64 FR 12887), entitled ''Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin.'' The SECG is intended to set forth the requirements of that final rule in plain language and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments concerning this SECG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for single copies of the SECG to Lori A. LeGault (address below). Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Lori A. LeGault, Center for Food Safety and Applied Nutrition (HFS–840), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5269.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1997 (62 FR 61476), FDA published a proposed rule to amend the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin.'' A final rule based on that proposed rule was published in the **Federal Register** of March 16, 1999 (64 FR 12887).

FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–602). The agency determined that the final rule would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Fairness Act (Public Law 104–121), FDA made available (via the Internet) a small entity compliance guide stating in plain language the requirements of this regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An