

neither an environmental assessment nor an environmental impact statement is required.

Dated: September 25, 2003.

Laura M. Tarantino,

Deputy Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the National Center for Food Safety and Technology; Notice of Intent to Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), announces its intent to award on an urgent basis, a single-source, program expansion supplement to the current cooperative agreement with the Illinois Institute of Technology (IIT) for \$1.1 million in fiscal year (FY) 2004. This cooperative agreement provides support for the National Center for Food Safety and Technology (NCFST), which is located on IIT's Moffett Campus in Summit-Argo, IL. The additional funding will enable IIT to undertake two new food contaminant mitigation projects and to continue the build-out of the biosafety level 3 (BSL-3) laboratory that began last year.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Maura Stephanos, Division of Contracts and Grants Management (HFA-531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7183, e-mail: mstepha1@oc.fda.gov.

Regarding the programmatic aspects: Karen Carson, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1664, e-mail: kcarson@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Restricted Eligibility

Assistance will be provided to IIT for the following reasons:

1. As part of FDA's food safety and security program, development of effective mitigation strategies requires a better understanding of food processing techniques that could be used to reduce the likelihood that contaminants persist in food following processing. This type of research requires expertise in food processing and packaging in addition to the availability of facilities and equipment appropriate to this type of research. The IIT/NCSFT has these resources. Additionally, IIT/NCSFT has available through this collaborative research program, the scientific and practical experience in a wide variety of food commodities and processing techniques that will feed into the development of mitigation strategies. This research will build on the ongoing food safety research program.

2. Last fiscal year FDA provided funds to IIT to expand the existing BSL-3 pilot plant facility to include BSL-3 laboratories. This is the only BSL-3 food processing pilot plant to which FDA has ready access. Expansion of the BSL-3 pilot plant facility will provide critical support to the overall research and will provide the flexibility to have more than one ongoing research project at a time. The additional funds will assure full operation of the facility and implementation of security measures consistent with Federal, State, and local requirements. Supplemental funds will allow the work on the BSL-3 pilot plant to be completed as quickly as possible.

II. Funding

It is anticipated that \$1.1 million will be made available to fund this urgent, single-source, program expansion supplement in FY 2004.

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labels, Packaging, Restaurants, and Weight Management; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Department of Health and Human Service's Office of the Assistant Secretary for Planning and Evaluation

(OASPE) and FDA's Center for Food Safety and Applied Nutrition (CFSAN), is announcing a public workshop entitled "Exploring the Connections Between Weight Management and Food Labels and Packaging." The workshop is being held in response to the growing concern about obesity in the United States. It is intended to be a science workshop (i.e., nutrition, consumer science, economics, marketing and other relevant sciences) that will look at available data to identify options (and pros and cons) about FDA's food labeling and food packaging requirements that are relevant to consumer weight management decisions.

DATES: The public workshop will be held on November 20, 2003, from 8:30 a.m. to 6 p.m.

Location: The public workshop will be held at the Lister Hill Conference Center, National Institutes of Health Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT:

Amber Jessup, Center for Food Safety and Applied Nutrition (HFS-726), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1689, amber.jessup@fda.gov.

Registration: There is no registration fee for the workshop; however, seating is limited. Therefore, interested parties are encouraged to register early. You may register online by clicking on <https://secure.z-techcorp.com/cmt/> (FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). All those planning to preregister must register no later than Friday, November 7, 2003. Registration will close after the workshop is filled. Onsite registration will be done on a space-available basis on the day of the public workshop beginning at 8 a.m. If you have any questions, please contact Karen Ellis at 301-315-2806 or via e-mail at kellis@z-techcorp.com. If you need special accommodations due to a disability, please contact Ms. Ellis at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the growing concern about obesity in the United States. The workshop is co-sponsored by FDA, CFSAN and OASPE. The workshop will be of primary interest to nutritionists, marketing experts, social marketing experts, industry, the legal community involved in food labeling and marketing issues, government agencies, consumer groups, and clinicians with obesity expertise. The goal of this science workshop is to

look at the available data and to identify options (pro & con) for food labeling and food packaging, which are relevant to consumers' weight management decisions. Topics to be discussed at the workshop include: "Current food labels and packaging: Effects on weight management and reduced risk of overweight and obesity" and "Data supporting options for change." The workshop will include sessions with expert views on food packaging and labeling, and on messaging in the restaurant environment relevant to overall weight management.

Transcripts: Transcripts of the public workshop 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 public workshop at a cost of 10 cents per page.

Dated: October 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0470]

Preparation for the International Conference on Harmonisation Meetings and ICH 6 Conference in Osaka, Japan; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Meetings and ICH 6 Conference in Osaka, Japan, November 9-15, 2003" to provide information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Osaka, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Experts Working Groups meetings and ICH 6 Public Conference in Osaka, Japan, November 2003, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on November 3, 2003, from 1 p.m. to 4 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3d floor, Twinbrook Conference Room, Rockville, MD 20857.

Contact Person: Christelle Anquez, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20817, 301-827-0037, FAX: 301-480-0716, *e-mail:* canquez@oc.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 October 24, 2003. If you need special accommodations due to a disability, please contact Christelle Anquez at least 7 days in advance.

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.

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. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. 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 (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. 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 at the following Web site: <http://www.ich.org> (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

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 3:15 p.m. and 4 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 October 24, 2003, 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 October 17, 2003, via the Internet at <http://www.fda.gov/cder/calendar/meeting/ich2003/nov3meeting.htm>.

Information on the ICH 6 Public Conference in Osaka, Japan on November 12-15, 2003, can be obtained via the internet at <http://www.ich.org/ich6tris.html> (FDA has verified the Web site address, but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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