Date and Time: See table 1 following the ''Location'' section of this document.

Location: See table 1 below

TABLE1

Meeting Address	Date and Local Time	FDA Contact Person
NEW JERSEY: Sheraton Meadowlands Hotel, 2 Meadowlands Plaza, East Rutherford, NJ, 201–896–0500.	Monday, June 17, 2002, from 8:30 a.m. to 4:30 p.m.	Erik N. Henrikson
PUERTO RICO: San Juan Marriott Hotel, 1309 Ashford Ave., San Juan, PR, 800–981–8546.	Monday, July 15, 2002, from 8:30 a.m. to 4:30 p.m.	Do.
CALIFORNIA: Manhattan Beach Marriott Hotel, 1400 Parkview Dr., Manhattan Beach, CA, 310–546–7511.	Monday, August 5, 2002, from 8:30 a.m. to 4:30 p.m.	Do.

Contact:

For information regarding participation by FDA: Erik N. Henrikson, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–827–0072, FAX 301–594–2202.

For information regarding the program or registration: Bill Bradley, Consumer Healthcare Products Association (CHPA), 1150 Connecticut Ave. NW., Washington, DC 20036, 202–429–9260, FAX 202–223–6835.

Registration: Anyone interested in the workshops can obtain registration information from Bill Bradley, CHPA (address above), or a brochure with the program and registration form is available at http://www.chpa-info.org/meetings/pdfs/2002workshops_updated_22602.pdf. This material is also available from http://www.fda.gov.cder/calendar. Space is limited. Please preregister by the Friday prior to each of these meetings to confirm your participation. If you need special accommodations due to a disability, please contact Erik N. Henrikson (address above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Who Should Attend? This announcement is directed toward professionals involved in the manufacture, control, and regulation of prescription or over-the-counter drugs who will benefit from these workshops, including: Process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, repackers and relabelers, consultants, regulatory investigators and good manufacturing practice compliance officials, and reviewing chemists. Other entities or individuals may also be interested in attending.

Is There a Registration Fee for This Workshop? Yes, a registration fee of $320.00 payable to CHPA is required for this workshop. This registration fee includes workshop reference materials and lunch on each day. Government employees qualify for a discounted rate of $75.00.

How Can I Get Additional Information, Including Copies of This Document or Other Related Documents? The notice of participation form, information about the workshops, and other related documents are available from the information contacts (addresses above) or on the Internet at http://www.fda.gov.cder/calender.

Dated: March 22, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7579 Filed 3–28–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA Food Labeling and Allergen Declaration; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs Southwest Regional Small Business Program (Small Business Program), in collaboration with FDA's Center for Food Safety and Applied Nutrition and the Mid-Continental Association of Food and Drug Officials is announcing a public workshop entitled ''FDA Food Labeling and Allergen Declaration.'' This public workshop is intended to provide information about FDA food labeling regulations, allergen declaration and other related matters to the regulated industry, particularly small businesses and startups.

Date and Time: The public workshop will be held on August 14 and 15, 2002, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Center for Community Cooperation, Oak Corner Room, 2900 Live Oak St., Dallas, TX 75204.

Contact: David Arvelo or Sue Thomason, Southwest Regional Office (HFR–SW16), Food and Drug Administration, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247, 214–655–8100, ext. 130 or 128, FAX 214–655–8114, or e-mail: oraswrsbr@ora.fda.gov.

Registration: Pre-registration by July 31, 2002, is encouraged. The Mid-Continental Association of Food and Drug Officials has a $25 pre-registration fee to cover the cost of breaks. To pre-register, please complete the form below and send along with a check or money order for $25 payable to the Mid-Continental Association of Food and Drug Officials, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247. As an alternative, the registration form can also be obtained on the Internet at http://www.fda.gov/ora/indust_assit/Default.htm. Directions to the facility are available at the Center for Community Cooperation Web site at http://www.cccdfw.org/pages/location.html. Seats are limited, please submit the registration form as soon as possible. Space will be filled in order of receipt of registration. Those accepted into the public workshop will receive written confirmation. 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. The cost of onsite registration is $35 payable to the Mid-Continental Association of Food and Drug Officials. If you need special accommodations due to a disability, please contact David Arvelo or Sue Thomason at least 7 days in advance.

The following information is requested for registration:

Name: _____

Agency: _____

Mailing address: _____

_____

City: _____ State:_____

Zip code: _____

Phone: ( ) _____

FAX: ( ) _____

E-mail: _____

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers

and startups originating from the Dallas District area. The Small Business Program presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about food allergens. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling, (3) claims, (4) allergen policy, and (5) labeling of special cases. FDA expects that participation in this workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and allergen declaration.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Workshop handouts 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: March 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7583 Filed 3–28–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0314]

"Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs)'' dated March 2002. The document is intended to provide guidance to sponsors on the design, development, organization, and submission in electronic format of an IND to the Center for Biologics Evaluation and Research (CBER). This guidance finalizes the draft guidance that was announced in the **Federal Register** on June 1, 1998 (63 FR 29741).

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

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document 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.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs)'' dated March 2002. The agency has developed this guidance to assist sponsors on the design, development, organization, and submission in electronic format of INDs to CBER. The guidance announced in this notice finalizes the draft ''Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products'' dated May 1998 (63 FR 29741, June 1, 1998).

This document reflects CBER's experience with the electronic IND pilot program and incorporates knowledge gained from development of the electronic marketing applications guidance document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Applications (NDA)]'' November 12, 1999 (64 FR 61647), revised. The agency also incorporated suggestions and recommendations from sponsors in developing a table of contents driven navigational system. However, this guidance does not address the scientific, clinical, and regulatory requirements for preparing an IND submission. These requirements can be found in title 21 of the Code of Federal Regulations, part 312 (21 CFR part 312). Part 312 must be followed in the preparation of any IND.

FDA currently is working on electronic submissions in the Common Technical Document (CTD) format developed by the International Conference on Harmonization (ICH). As FDA develops guidance on electronic CTD submissions, CBER intends to harmonize this guidance with the CTD guidance. This guidance describes how sponsors may submit electronic INDs to CBER. Sponsors may continue to submit INDs in paper form.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. 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 requirement