

1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action prior to its termination. Section 1868(a) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

The Council held its first meeting on May 11, 1992. The current members are: James Bergeron, M.D.; Ronald Castallanos, M.D.; Rebecca Gaughan, M.D.; Carlos R. Hamilton, M.D.; Joseph Heyman, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Christopher Leggett, M.D.; Barbara McAneny, M.D.; Angelyn L. Moultrie-Lizana, D.O.; Laura B. Powers, M.D.; Michael T. Rapp, M.D.; Amilu Rothhammer, M.D.; Robert L. Urata, M.D.; and Douglas L. Wood, M.D. The meeting will commence with a Council update on the status of prior recommendations, followed by discussion and comment on the following agenda topics:

- Physician's Regulatory Issues Team (PRIT).
- Power Operated Vehicles.
- Current Status on Physicians Providing Professional Courtesies.
- Provider Communications (GAO Report 02-249: Communications with Physicians can be Improved; February 2002).
- Outpatient Prospective Payment System for CY 2004 and Physician Fee Schedule Final Rules for CY 2004.
- Update on Current Procedural Terminology/Evaluation and Management Coding Guidelines.
- Update on Prescription Drug Card Benefit.
- End Stage Renal Disease (ESRD) Quality Initiative.
- IG Statutory Authority and FY 2004 Work Plan.

For additional information and clarification on these topics, contact the Executive Director, listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues should contact the Executive Director by 12 noon, October 31, 2003, to be scheduled. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to Diana Motsiopoulos, Administrative Coordinator, no later

than 12 noon, November 7, 2003, for distribution to Council members for review prior to the meeting. Physicians and medical organizations not scheduled to speak may also submit written comments to the Administrative Coordinator for distribution. The meeting is open to the public, but attendance is limited to the space available. *Special Accommodations:* Individuals requiring sign language interpretation or other special accommodation should contact Diana Motsiopoulos by e-mail at [dmotsiopoulos@cms.hhs.gov](mailto:dmotsiopoulos@cms.hhs.gov) or by telephone at (410) 786-3379 at least 10 days before the meeting.

**Authority:** Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 17, 2003.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999N-1168]

#### Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat-Foods; Risk Assessment; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS), in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC) of HHS, are announcing the availability of a quantitative risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health that considers 23 ready-to-eat food categories.

**ADDRESSES:** Submit written requests for single copies of the risk assessment document and CD-ROM of the model, to Sherri Dennis, Center for Food Safety and Applied Nutrition (CFSAN) (see

**FOR FURTHER INFORMATION CONTACT**). The document is entitled "Quantitative Assessment of Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat-Foods." Send one self-adhesive label with your address to assist that office in processing your request. You also may request a copy of the risk assessment document by faxing your name and mailing address with the name of the document you are requesting to the CFSAN Outreach and Information Center at 1-877-366-3322. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

A copy of the risk assessment document may be reviewed at the FDA Division of Dockets Management (HFA-305)(Docket No. 99N-1168) at 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, and at the FSIS Docket Clerk's Office (Docket No. 00-048N), U.S. Department of Agriculture, rm. 102, Cotton Annex, 300 12th St. SW., Washington, DC 20250, between 8:30 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS-006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740, 301-436-1914.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of January 19, 2001 (67 FR 5515), FDA and FSIS announced the availability of a draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health that considers categories of ready-to-eat food. FDA, FSIS, and CDC held a public meeting on March 19, 2001 (66 FR 13544), to receive comments on the technical aspects of the draft risk assessment. Interested persons were given until March 20, 2001, with extensions to May 21, 2001, and to July 18, 2001, to comment on the document. The risk assessment has been revised in response to the public comments, newly available data, and updated modeling techniques.

#### II. Risk Assessment

The purpose of the quantitative risk assessment is to examine systematically available scientific data and information to estimate the relative risks of serious illness and death associated with consumption of different types of ready-to-eat foods that may be contaminated with *L. monocytogenes*. This

examination of the current science and the models developed from it are among the tools available to FDA and FSIS to evaluate the effectiveness of current and future policies, programs, guidance, and regulatory practices to minimize the public health impact of this pathogen.

Quantitative risk assessment of microbial pathogens is a structured process of collecting and evaluating data and information to assess the risks to human health from consumption of pathogenic microorganisms. The risk assessment evaluates the available data on food consumption, contamination by *L. monocytogenes* of various foods within 23 ready-to-eat food product categories, growth of the pathogen in such foods, and the infectious dose. The risk assessment follows the framework recommended both by the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

(1) *Hazard Identification*. The collection and critical review of data and information on health effects associated with consumption of *L. monocytogenes*.

(2) *Exposure Assessment*. The determination of exposure to *L. monocytogenes* from consumption of various foods using prevalence and food consumption data.

(3) *Hazard Characterization/ Dose-response*. The description of the relationship between *L. monocytogenes* exposure level and frequency of severe illness or mortality using epidemiological investigations and data from animal studies.

(4) *Risk Characterization*. The integration of the exposure and dose-response data to estimate both the risk to the public health and the uncertainty associated with this estimate.

The risk assessment provides estimates of the number of cases of listeriosis associated with consumption of 23 ready-to-eat food categories on both a per serving and per annum basis and provides, though the assignment of predicted relative risk rankings, a means of comparing the relative risks among the different food categories and different population groups. The results of the risk assessment reinforce past epidemiological conclusions that foodborne listeriosis is a moderately rare but severe disease and that certain foods are more likely to be vehicles for *L. monocytogenes* and associated with outbreaks and sporadic illnesses.

Consumer exposure to *L. monocytogenes* at the time of consumption is affected by these five factors: (1) Amounts and frequency of consumption of a ready-to-eat food, (2)

frequency and levels of *L. monocytogenes* in a ready-to-eat food, (3) potential of the food to support growth of *L. monocytogenes* during refrigeration, (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption. In interpreting the results of the risk assessment, the food categories were divided into five overall risk designations based on different approaches needed to control foodborne listeriosis.

### III. Electronic Access

The risk assessment document is available electronically at [www.cfsan.fda.gov](http://www.cfsan.fda.gov), [www.fsis.usda.gov](http://www.fsis.usda.gov), [www.foodsafety.gov](http://www.foodsafety.gov), and [www.foodriskclearinghouse.umd.edu](http://www.foodriskclearinghouse.umd.edu).

Dated: October 10, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Customs and Border Protection

#### U.S. Customs and Border Protection Trade Symposium 2003

**AGENCY:** U.S. Customs and Border Protection, Homeland Security.

**ACTION:** Notice of trade symposium.

**SUMMARY:** This document announces that U.S. Customs and Border Protection (CBP) will convene a major trade symposium that will feature joint discussions by Department of Homeland Security and CBP personnel, members of the trade community, and other public and private sector representatives on the agency's role in the new Department, international trade security initiatives and the unification of functions at the border. Commissioner Robert C. Bonner will be the keynote speaker. Members of the international trade and transportation communities and other interested parties are encouraged to attend, and those attending are requested to register early.

**DATES:** Check-in and a reception will be held on Wednesday, November 19, 2003, from 6 p.m. until 8 p.m. The symposium will be held on Thursday, November 20, 2003, from 8:30 a.m. until 6 p.m. and on Friday, November 21, 2003, from 8 a.m. until 12 p.m. All registrations must be made on-line and confirmed with payment on a space-available basis by November 14th.

**ADDRESSES:** The Trade Symposium of 2003 will be held in Washington, DC, at

the Ronald Reagan Building and International Trade Center, at 1300 Pennsylvania Avenue, NW. Check-in and a reception will be held in the Pavilion Room on Wednesday, November 19th. The symposium will be held in the Amphitheater on Thursday, November 20th, and in the Atrium Ballroom on Friday, November 21st.

**FOR FURTHER INFORMATION CONTACT:** ACS Client Representatives; CBP Account Managers; Regulatory Audit Trade Liaisons; or the Office of Trade Relations at (202) 927-1440 or at [traderelations@dhs.gov](mailto:traderelations@dhs.gov). To obtain the latest information on the program or to register on-line, visit the CBP Web site at <http://www.cbp.gov>. Requests for special needs should be sent to the Office of Trade Relations at [traderelations@dhs.gov](mailto:traderelations@dhs.gov).

**SUPPLEMENTARY INFORMATION:** U.S. Customs and Border Protection (CBP) will be convening a major trade symposium (U.S. Customs and Border Protection Trade Symposium 2003) on Thursday, November 20, 2003, from 8:30 a.m. until 6 p.m. and on Friday, November 21, 2003, from 8 a.m. until 12 p.m. at the Ronald Reagan Building and International Trade Center, 1300 Pennsylvania Avenue, NW., Washington, DC. The symposium will feature joint discussions by Department of Homeland Security and CBP personnel, members of the trade community, and other public and private sector representatives on the agency's role in the new Department, international trade security initiatives and the unification of functions at the border. Commissioner Robert C. Bonner will be the keynote speaker. Members of the international trade and transportation communities and other interested parties are encouraged to attend.

The cost is \$150 per individual and includes all symposium activities. Interested parties are requested to register early, as space is limited. All registrations must be made on-line at the CBP Web site (<http://www.cbp.gov>). Registrations will be accepted on a space-available basis and must be confirmed with payment by November 14, 2003. The Renaissance Washington DC Hotel, 999 9th Street, NW., has reserved a block of rooms for Wednesday, November 19th and Thursday, November 20th at a rate of US\$189 per night. Reservations must be confirmed with the hotel by October 31st. Call 202-898-9000 or 1-800-228-9290 and reference the "CBP Trade Symposium."