DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee (SRSHES): Conference Call Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee.

Time and Date: 10:30 a.m.—11:30 a.m., May 31, 2001.

Place: The conference call will originate at the National Center for Environmental Health (NCEH), CDC, in Atlanta, Georgia. Please see ''Supplementary Information'' for details on accessing the call.

Status: Open to the public, limited only by the availability of telephone ports.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site.

Matters to be Discussed: The conference call agenda is to reach consensus on membership issues. Agenda items are subject to change as priorities dictate.

Supplementary Information: This conference call is scheduled to begin at 10:30 a.m., Eastern Time. To participate in the conference call, please dial 800/311–3437 and enter conference code 375443. You will then be automatically connected to the call.

This notice is being published less than 15 days prior to the meeting due to the scheduling conflicts of the members.

Contact Person for More Information: Paul Renard, Executive Secretary, SRSHES, and Chief, Extramural Activities Section, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, N.E. (E–39), Atlanta, GA 30333, telephone 404/639–2550, fax 404/639–2575.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: May 16, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–12815 Filed 5–21–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Grant Program for Strategies for Improving Health Risk Communication Related to Military Deployments Among Military Personnel, Veterans, Their Family Members, and Their Health Care Providers, PA# 01021; Correction

SUMMARY: This notice was published in the **Federal Register** on April 30, 2001, Volume 66, Number 83, Pages 21388–21389. The meeting times and dates have been revised.

DATES: The meeting times and dates have been revised as follows:

9 a.m.–9:30 a.m., June 4, 2001 (Open)
9:30 a.m.–Noon, June 4, 2001 (Closed)

FOR FURTHER INFORMATION CONTACT: Drue Barrett, Ph.D., Chief, Veterans' Health Activity Working Group, National Center for Environmental Health, CDC, 1600 Clifton Rd, NE, MS E–19, Atlanta, Ga. 30333. Telephone 404/639–4862, e-mail dhb1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 16, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–12818 Filed 5–21–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1168]

Relative Risk to Public Health From Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS, and Food Safety and Inspection Service, USDA.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention, published a notice of availability of a draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health and a proposed risk management action plan for *L. monocytogenes* in the **Federal Register** of January 19, 2001 (66 FR 5515). Interested persons were given until March 20, 2001, with an extension to May 21, 2001 (66 FR 13545), to comment on these documents. The LM Working Group has requested a second extension of the comment period in part to collect and review new data and to evaluate the model and the appropriateness of the new data to improve the assessment. In response, FDA and USDA/FSIS are extending the comment period to July 18, 2001; however, the agencies do not anticipate further extensions of the comment period for these draft documents.

DATES: Submit written comments by July 18, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Docket No. 99N–1168, Food

and Drug Administration, 5630 Fishers Lane, rm. 1060, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Received comments may be reviewed at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00–048N, U.S. Department of Agriculture, Food Safety and Inspection Service, rm. 102, Cotton Annex, 300 12th St, SW., Washington, DC 20250–3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information concerning the draft risk assessment document: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, e-mail: sdennis@cfsan.fda.gov.

For information concerning the risk management action plan: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4231, FAX 202–260–0136, e-mail: kgombas@cfsan.fda.gov or Charles Edwards, Food Safety and Inspection Service, U.S. Department of Agriculture, rm. 405, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700, 202–205–0675, FAX 202–205–0080.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2001 (66 FR 5515), the Department of Health and Human Services and USDA announced the availability of two documents: A draft risk assessment on the relationship between foodborne *L. monocytogenes* and human health and a draft risk management action plan. Comments were sought on the technical aspects of the draft risk assessment in the following areas: (1) The assumptions made, (2) the modeling technique, (3) the data used, and (4) the transparency of the draft risk assessment document. The agencies also invited comments on the risk management strategies as presented in the draft action plan. Interested persons were given until March 20, 2001, to comment on the draft risk assessment and draft action plan. FDA and USDA/FSIS extended the comment period to May 21, 2001 (66 FR 13545, March 6, 2001), in response to the requests of the National Food Processors Association and the LM Working Group and because a public meeting to receive comments on these documents was scheduled on March 19, 2001, only 1 day before the close of the comment period. The LM Working Group has requested a second extension of the comment period in part to allow time to: (1) Collect and review new data, and (2) evaluate the model and the appropriateness of the new data to improve the assessment. In response, FDA and USDA/FSIS are extending the comment period to July 18, 2001; however, the agencies do not anticipate further extensions of the comment period for these draft documents.

To be considered, submit written comments to FDA Dockets Management Branch or the FSIS Dockets Clerk (addresses above) by July 18, 2001.

Printed copies of the draft risk assessment and the risk management action plan and/or a CD–ROM of the risk assessment model may be requested by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. The documents may be reviewed at the FDA Dockets Management Branch or the FSIS Docket Clerk's Office at the addresses and hours noted above. The draft risk assessment and action plan documents are also available electronically as follows: www.cfsan.fda.gov, www.fsis.usda.gov, www.foodsafety.gov.

Dated: May 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13055 Filed 5–18–01; 2:59 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4071]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry on ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients'' (VICH GL18); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#100) entitled ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients'' (VICH GL18). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a similarly titled guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the final guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in the final guidance) submitted to the European Union, Japan, and the United States.

DATES: You may submit written comments at any time.

ADDRESSES: You may submit written requests for a single copy of the final guidance entitled ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients'' (VICH GL18) to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

You may submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kevin J. Greenlees (HFV–150), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, e-mail, kgreenle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has