Severe Problems

• Serious allergic reaction (very rare)

6. What If There Is a Moderate or Severe Reaction?

What Should I Look For?

Any unusual condition, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If such a reaction were to occur, it would be within a few minutes to a few hours after the shot.

What Should I Do?

• Call a doctor or get the person to a doctor right away.
• Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
• Ask your doctor, nurse, or health department to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1–800–822–7967.

7. The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1–800–338–2382 or visit the program's website at *http://www.hrsa.gov/bhpr/vicp*

8. How Can I Learn More?

• Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department's immunization program.
• Contact the Centers for Disease Control and Prevention (CDC):
—Call 1–800–232–2522 or 1–888–443–7232 (English)
—Call 1–800–232–0233 (Español)
—Visit the National Immunization Program's website at *http://www.cdc.gov/nip* or CDC's Hepatitis Branch website at *http://www.cdc.gov/ncidod/diseases/hepatitis*

Department of Health & Human Services, Centers for Disease Control and Prevention, National Immunization Program

Vaccine Information Statement
Hepatitis B
(00/00/0000) (Proposed)
42 U.S.C. 300aa–26

Dated: February 28, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–5377 Filed 3–5–01; 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; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

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 is announcing the following public meeting: 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. The purpose of the public meeting is to receive comments on the technical aspects of a draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health, and on a proposed risk management action plan for *L. monocytogenes*. A notice of availability of the draft risk assessment and the action plan was published in the **Federal Register** of January 19, 2001 (66 FR 5515).

Date and Time: The meeting will be held on March 19, 2001, 8:30 a.m. to 4 p.m.

Location: The meeting will be held at the Hilton Hotel, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–6), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251, FAX 202–205–4970, e-mail: cderoeve@cfsan.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), to the contact person by March 14, 2001. Interested persons may present data, information, or views orally or in writing, on the issues identified above. Written submissions must also be made to the contact person by March 14, 2001. Time allotted for each presentation may be limited. If you wish to make a formal oral presentation, you should notify the contact person before March 14, 2001, and be prepared to provide a brief statement of the general nature of the evidence you wish to present.

If you need special accommodations due to a disability, please contact Catherine M. DeRoever (address above) 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 U. S. Department of Health and Human Services and the USDA are seeking comments 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. All public comments will be reviewed and evaluated, and the assessment will be modified, as appropriate. The agencies are also inviting comments on the risk management strategies as presented in the draft action plan.

Dated: February 28, 2001.

Ann M Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–5379 Filed 3–1–01; 4:23 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1075]

Public Health Impact of Vibrio Parahaemolyticus in Raw Molluscan Shellfish; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting on: *Vibrio parahaemolyticus* in raw molluscan shellfish and human health. The purpose of the meeting is to receive comments on the technical aspects of the draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan

shellfish and human health. Notice of availability of the draft risk assessment was previously published in the **Federal Register** of January 19, 2001.

Date and Time: The meeting will be held on March 20, 2001, 9 a.m. to 3 p.m.

Location: The meeting will be held at the Hilton Hotel-Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–6), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–251, FAX 202–205–4970, e-mail cderoeve@cfsan.fda.gov.

Agenda: FDA is seeking comments on 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. FDA will review and evaluate all public comments and make modifications to the risk assessment, as appropriate.

Registration and Requests for Oral Presentation: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by March 14, 2001. Interested persons may present data, information, or views orally or in writing, on the draft risk assessment on the relationship between *V. parahaemolyticus* in raw molluscan shellfish and human health. Written submissions must also be made to the contact person by March 14, 2001. Time allotted for each presentation may be limited. If you wish to make a formal oral presentation, you should notify the contact person before March 14, 2001, and be prepared to provide a brief statement of the general nature of the evidence you wish to present.

If you need special accommodations due to a disability, please contact Catherine M. DeRoever (address above) 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.

Dated: February 28, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–5462 Filed 3–1–01; 4:23 pm]

BILLING CODE 4162–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1168]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00-048N]

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. Interested persons were given until March 20, 2001, to comment on these documents. Because a public meeting to receive comments on these documents has been scheduled close to the end of the comment period and in response to the requests of the National Food Processors Association and the LM Working Group for an extension of the comment period, FDA and FSIS are extending the comment period until May 21, 2001.

DATES: Submit written comments by May 21, 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 Street 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.

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 risk management action plan. Because a public meeting to receive comments on these documents has been scheduled close to the end of the comment period, and in response to the requests of the National Food Processors Association and the LM Working scheduled close to the end of the comment period, and in response to the requests of the National Food Processors Association and the LM Working Group for an extension of the comment period, FDA and FSIS are extending the comment period until May 21, 2001.

To be considered, submit written comments to FDA Dockets Management Branch or the FSIS Dockets Clerk (addresses above) by May 21, 2001.

Printed copies of the draft risk assessment and the risk management action plan may be requested by faxing your name and mailing address with the