

practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections in U.S. healthcare facilities. The committee advises CDC on guidelines and other policy statements regarding prevention of healthcare-associated infections and related adverse events.

Dated: February 28, 2001.

Joseph R. Carter,

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

[FR Doc. 01-5376 Filed 3-5-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Vaccine Information Materials for Pneumococcal Conjugate, Diphtheria, Tetanus, Acellular Pertussis (DTaP/DT) and Hepatitis B Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on proposed new vaccine information materials for pneumococcal conjugate vaccine, and revised vaccine information materials for diphtheria, tetanus, acellular pertussis (DTaP/DT) vaccines and hepatitis B vaccine.

DATES: Written comments are invited and must be received on or before May 7, 2001.

ADDRESSES: Written comments should be addressed to Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT: Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act

of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since June 1, 1999, health care providers are also required to provide copies of vaccine information materials for the following vaccines that were added to the National Vaccine Injury Compensation Program: hepatitis B, haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines. Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC website at: <http://www.cdc.gov/nip/publications/VIS/>. In addition, single camera-ready copies are available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in

a December 17, 1999 **Federal Register** notice (64 FR 70914).

Pneumococcal Conjugate Vaccine Information Materials

With the December 18, 1999, addition of pneumococcal conjugate vaccine to the National Vaccine Injury Compensation Program, CDC, as required under 42 U.S.C. 300aa-26, is proposing vaccine information materials covering that vaccine, which are included in this notice.

Revised Vaccine Information Materials for Diphtheria, Tetanus, Acellular Pertussis (DTaP/DT) Vaccines and Hepatitis B Vaccine

This notice also includes proposed revised vaccine information materials for diphtheria, tetanus and acellular pertussis vaccines (other than Td vaccine) and hepatitis B vaccine.

The DTaP/DT materials are being revised to remove references to DTP (whole cell pertussis-containing vaccine) because this vaccine is no longer used in the United States. In addition, these proposed revised materials reflect a new adverse event profile for DTaP, including updated adverse event information on acellular pertussis vaccine.

The hepatitis B materials are being revised to note a recently approved two dose schedule for administration to adolescents 11 to 15 years of age as an alternative to the three dose schedule. Interim revised hepatitis B vaccine information materials were published in a September 1, 2000 **Federal Register** notice (65 FR 53316) for use pending completion of the formal revision process.

Development of New/Revised Vaccine Information Materials

The proposed vaccine information materials included in this notice were drafted in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, the American Academy of Pediatrics, American Pharmaceutical Association, Association of American Indian Physicians, Every Child by Two, Immunization Action Coalition, Immunization, Education and Action Committee, Infectious Disease Society of America, National Association for Pediatric Nurse Associates and Practitioners and the National Vaccine Advisory Committee. Also, CDC provided copies of the draft materials to other organizations and sought their consultation; however, those organizations did not provide comments. Comments provided by the consultants were considered in drafting

the proposed vaccine information materials included in this notice.

We invite written comment on the proposed vaccine information materials that follow, entitled "Pneumococcal Conjugate Vaccine: What You Need to Know," "Diphtheria, Tetanus & Pertussis Vaccines: What You Need to Know," and "Hepatitis B Vaccine: What You Need to Know." Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their use.

We also propose to revise the December 17, 1999, Instructions for Use of Vaccine Information Materials (Vaccine Information Statements), and interim instructions dated September 6, 2000, to add the requirement for use of the pneumococcal conjugate vaccine information materials and to note the new edition dates for the revised vaccine information materials covering diphtheria, tetanus, pertussis (DTaP/DT) vaccines and hepatitis B vaccine.

Pneumococcal Conjugate Vaccine: What You Need to Know

1. Why Get Vaccinated?

Pneumococcal disease is a serious disease that causes sickness and death. In fact, it is the leading cause of bacterial meningitis in the United States. (Meningitis is a serious infection of the covering of the brain).

Each year pneumococcal disease causes in children under five:

- 17,000 cases of invasive disease, including 700 cases of meningitis
- About 5 million ear infections
- About 200 deaths

It can also lead to other health problems, including:

- Pneumonia
- Deafness
- Brain damage

Children under 2 years old are at highest risk for serious disease.

Pneumococcus bacteria are spread from person to person through close contact.

Pneumococcal infections can be hard to treat because some bacteria have become resistant to drugs that have been used to treat them. This makes prevention of the disease even more important.

Pneumococcal conjugate vaccine can prevent serious pneumococcal disease, such as meningitis and blood infections. It also prevents some ear infections. But ear infections have many causes, and pneumococcal vaccine is effective against only some of them.

2. Pneumococcal Conjugate Vaccine

Pneumococcal conjugate vaccine is approved for infants and toddlers. Protection lasts at least 3 years, so children who are vaccinated as infants will be protected when they are at greatest risk for serious disease.

Some older children and adults may get a different vaccine called pneumococcal polysaccharide vaccine. There is a separate Vaccine Information Statement for people getting the pneumococcal polysaccharide vaccine.

3. Who Should Get the Vaccine and When?

Children under 2 years of age:

- 2 months
- 4 months
- 6 months
- 12–15 months

Children who weren't vaccinated at these ages can still get the vaccine. The number of doses needed depends on the child's age. Ask your health care provider for details.

- Children between 2 and 5 years of age:

Pneumococcal conjugate vaccine is also recommended for children between 2 and 5 years old who have not already gotten the vaccine and are at high risk of serious pneumococcal disease. This includes children who:

- Have sickle cell disease,
- Have a damaged spleen or no spleen,
- Have HIV/AIDS,
- Have other diseases that affect the immune system, such as diabetes, cancer, or liver disease, or
- Take medications that affect the immune system, such as chemotherapy or steroids.

Other children who are at increased risk of serious pneumococcal disease include those who:

- Are under 3 years of age,
- Are of Alaska Native, American Indian or African American descent, or
- Attend group day care.

The number of doses needed depends on the child's age. Ask your health care provider for more details.

Pneumococcal conjugate vaccine may be given at the same time as other routine childhood vaccines.

4. Some Children Should Not Get Pneumococcal Conjugate Vaccine or Should Wait

Children should not get pneumococcal conjugate vaccine if they had a severe (life-threatening) allergic reaction to a previous dose of this vaccine, or have a severe allergy to a vaccine component. Tell your health-care provider if your child has ever had

a severe reaction to any vaccine, or has any severe allergies.

Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting the vaccine.

5. What Are the Risks From Pneumococcal Conjugate Vaccine?

In clinical trials (nearly 60,000 doses), pneumococcal conjugate vaccine was associated with only mild reactions:

- Up to about 1 infant out of 4 had redness, tenderness, or swelling where the shot was given.
- About 1 out of 3 had a fever of over 100.4 °F, and up to about 1 in 50 had a higher fever (over 102.2 °F).
- Some children also became fussy or drowsy, or had a loss of appetite.

So far, no moderate or severe reactions have been associated with this vaccine. However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. The risk of this vaccine causing serious harm, or death, is extremely small.

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

What Should I Look For?

Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat, dizziness, and swelling of the throat.

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 health care provider to file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at 1-800-822-7967.

7. The 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 their 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 (English) or 1-800-232-0233 (Español)
 - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>

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

Vaccine Information Statement
Pneumococcal Conjugate Vaccine
(00/00/0000) (Proposed)
42 U.S.C. 300aa-26

Diphtheria, Tetanus & Pertussis Vaccines: What You Need To Know

1. Why Get Vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

Diphtheria causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

Tetanus (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in about 3 out of 10 cases.

Pertussis (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2. Who Should Get DTaP Vaccine and When?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

—2 months

—4 months

—6 months

—15-18 months

—4-6 years

DTaP may be given at the same time as other vaccines.

3. Some Children Should Not Get DTaP Vaccine or Should Wait

- Any child who has had a life-threatening allergic reaction after a dose of DTaP should not get any more doses.

- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get any more doses.

- Talk with your doctor if your child:
 - Had a seizure or collapsed after a previous dose of DTaP,

- Cried non-stop for 3 hours or more after a previous dose of DTaP,
- Had a high fever (over 105 °F) after a previous dose of DTaP.

- Children who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting DTaP vaccine.

Ask your health care provider for more information. Children who should not get the pertussis part of the vaccine can get a vaccine called DT, which doesn't contain pertussis.

4. Older Children and Adults

DTaP should not be given to anyone 7 years of age or older. Pertussis can still strike older children, adolescents, and adults, but the pertussis vaccine is currently licensed only for children under 7.

Adolescents and adults still need protection from tetanus and diphtheria. A booster shot called Td is recommended at 11-12 years of age. It should be repeated every 10 years. There is a separate Vaccine Information Statement for Td vaccine.

5. What Are the Risks From DTaP Vaccine?

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine. However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses.

Another mild problem is swelling of the arm or leg in which the shot was given, after the 4th or 5th dose (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1-3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105 °F (about 1 child out of 16,000)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures.

You can reduce fever and pain by giving your child an aspirin-free pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

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

What Should I Look For?

Any unusual conditions, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness within a few minutes to a few hours after the shot. If a high fever or seizure occurs, it is usually within 2 weeks 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 health care provider. 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 (English)
 - Call 1-800-232-0233 (Español)
 - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>

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

Vaccine Information Statement
DTaP
(00/00/0000) (Proposed)
42 U.S.C. 300aa-26

Hepatitis B Vaccine: What You Need To Know

1. *Why Get Vaccinated?*

Hepatitis B Is a Serious Disease

The hepatitis B virus can cause short-term (acute) illness that leads to:

- Loss of appetite
- Diarrhea and vomiting
- Tiredness
- Jaundice (yellow skin or eyes)
- Pain in muscles, joints, and stomach

It can also cause long-term (chronic) illness that leads to:

- Liver damage (cirrhosis)
- Liver cancer
- Death

About 1.25 million people in the U.S. have chronic hepatitis B virus infection. If you are infected as a young child, you are much more likely to develop chronic illness.

Each year it is estimated that:

- 200,000 people, mostly young adults, get infected with hepatitis B virus
- More than 11,000 people have to stay in the hospital because of hepatitis B
- 4,000 to 5,000 people die from chronic hepatitis B

Hepatitis B vaccine can prevent hepatitis B. It is the first anti-cancer vaccine because it can prevent a form of liver cancer.

2. *How Is Hepatitis B Virus Spread?*

Hepatitis B virus is spread through contact with the blood and body fluids of an infected person.

A person can get infected in several ways, such as:

- During birth when the virus passes from an infected mother to her baby
- By having sex with an infected person
- By injecting illegal drugs
- By being stuck with a used needle on the job
- By sharing personal items, such as a razor or toothbrush with an infected person

People can get hepatitis B infection without knowing how they got it. About 1/3 of hepatitis B cases in the United States have an unknown source.

3. *Who Should Get Hepatitis B Vaccine and When?*

- (1) Everyone 18 years of age and younger
- (2) Adults over 18 who are at risk

Adults at risk for hepatitis B infection include people who have more than one sex partner, men who have sex with other men, injection drug users, health care workers, and others who might be exposed to infected blood or body fluids.

If you are not sure whether you are at risk, ask your doctor or nurse.

People should get 3 doses of hepatitis B vaccine according to the following schedule. If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

HEPATITIS B VACCINATION SCHEDULE

When?	Who?		
	Infant whose mother is infected with hepatitis B virus	Infant whose mother is not infected with hepatitis B virus	Older child, adolescent, or adult
First Dose	Within 12 hours of birth	Birth-2 months of age	Any time.
Second Dose	1-2 months of age	1-4 months of age (At least 1 month after first dose).	1-2 months after first dose.
Third Dose	6 months of age	6-18 months of age	4-6 months after first dose.

The second dose must be given at least 1 month after the first dose.
The third dose must be given at least 2 months after the second dose and at least 4 months after the first.
The third dose should not be given to infants younger than 6 months of age.

Adolescents 11 to 15 years of age may need only two doses of hepatitis B vaccine, separated by 4-6 months. Ask your health care provider for details.

Hepatitis B vaccine may be given at the same time as other vaccines.

4. *Some People Should Not Get Hepatitis B Vaccine or Should Wait*

People should not get hepatitis B vaccine if they have ever had a life-threatening allergic reaction to baker's yeast (the kind used for making bread) or to a previous dose of hepatitis B vaccine.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting hepatitis B vaccine.

Ask your doctor or nurse for more information.

5. *What Are the Risks From Hepatitis B Vaccine?*

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Getting hepatitis B vaccine is much safer than getting hepatitis B disease.

Most people who get hepatitis B vaccine do not have any problems with it.

Mild Problems

- Soreness where the shot was given, lasting a day or two (up to 1 out of 11 children and adolescents, and about 1 out of 4 adults)
- Mild to moderate fever (up to 1 out of 14 children and adolescents and 1 out of 100 adults)

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