the cardholder's name and telephone number must be included on the packing list.

B. Annual Reporting Burden

Respondents: 4,000; annual responses: 931,219; average hours per response: .02; burden hours: 31.

Copy of Proposal

A copy of this proposal may be obtained from the GSA Acquisition Policy Division (MVP), Room 4011, GSA Building, 1800 F Street NW, Washington, DC 20405, or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: August 27, 1998.

Ida M. Ustad,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 98–23731 Filed 9–2–98; 8:45 am]

BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Vaccine Information Materials for Hepatitis B, Haemophilus influenzae type b (Hib), Varicella (Chickenpox), and Measles, Mumps, Rubella (MMR) 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), CDC must develop vaccine information materials that 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 hepatitis B, *Haemophilus influenzae* ype b, and *Varicella* vaccines, and revised vaccine information materials for measles, mumps, rubella (MMR) vaccines.

DATES: Written comments are invited and must be received on or before November 2, 1998.

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, N.E., 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, N.E., Atlanta, Georgia 30333, telephone (404) 639–8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Public Law 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 health care providers 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 who intends to administer one of the covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. (The materials currently in use for measles, mumps, and rubella vaccines and the tetanus diphtheria [Td] vaccine, were published in a **Federal Register** notice on June 20, 1994 (59 FR 31888). The current materials for polio vaccine were published in a **Federal Register** notice on February 6, 1997 (62 FR 5696), and, the current materials for diphtheria, tetanus, and pertussis containing vaccines, other than Td vaccine, were published in a **Federal Register** notice on January 9, 1998 (63 FR 1730). Instructions for use of the vaccine information materials and a list of contacts for obtaining copies of these materials are included in the January 9, 1998 **Federal Register** notice (63 FR 1730).)

Newly Covered Vaccines

With passage of Public Law 105–34, Congress expanded coverage of the National Vaccine Injury Compensation Program, effective August 6, 1997, to include the following additional vaccines: hepatitis B, *Haemophilus influenzae* type b (Hib), and *Varicella* (chickenpox) vaccines. (See 63 FR 25777, May 11, 1998, for information regarding coverage of these vaccines under the Vaccine Injury Compensation Program.) Therefore, as required under 42 U.S.C. 300aa-26, CDC must develop vaccine information materials covering these vaccines.

Included in this notice are proposed vaccine information materials covering hepatitis B, *Haemophilus influenzae t*ype b (Hib), and *Varicella* vaccines. In addition to proposed materials for these newly covered vaccines, this notice also includes proposed revised vaccine information materials for measles, mumps, rubella (MMR) vaccines. The MMR materials are being revised to follow the format of the materials published since 1997.

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, American Academy of Pediatrics, American Nurses Association, Dissatisfied Parents Together, Healthy Start, Immunization Action Coalition, Immunization Education and Action Committee: Healthy Mothers/Healthy Babies Coalition, National Association of Pediatric Nurse Associates and Practitioners, National Association of County Health Officials, National Coalition for Adult Immunization, National Coalition of Hispanic Health and Human Services Organizations (COSSMHO), National Council of La Raza, National Vaccine Advisory Committee, and the National Vaccine Injury Compensation Program. Also, CDC provided copies of the draft materials to other organizations and sought their consultation; however, those organizations did not provide comments. In addition to consultation with these groups, the CDC presented drafts of these vaccine information materials to parents gathered in 18 ethnically and geographically diverse

focus groups. Comments provided by the consultants and focus groups 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 ''Hepatitis B Vaccine: What You Need to Know,'' ''*Haemophilus influenzae* type b (Hib) Vaccine: What You Need to Know,'' ''Chickenpox Vaccine: What You Need to Know,'' and ''Measles, Mumps and Rubella Vaccines: 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.

* * * * *

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

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

- Liver damage (cirrhosis).
- Liver cancer.
- Death.

Each year in the United States it is estimated that,

- 64,000 people—mostly young adults—get hepatitis B.
- More than 11,000 people have to stay in the hospital because of hepatitis B.
- About 1.25 million people have chronic hepatitis B infection.
- 4,000–5,000 people die from chronic hepatitis B.

Hepatitis B vaccine can prevent hepatitis B. Hepatitis B vaccine 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 or 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.
- 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 one third 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:

- Men or women who have sex with more than one steady partner.
- Men or women who have recently gotten a sexually transmitted disease.
- Injection drug users.
- Men who have sex with other men.
- Household contacts and sex partners of persons with long-term hepatitis B.
- People whose job involves contact with human blood.
- People who live or travel for more than 6 months in countries where hepatitis B is common.
- Clients and staff in institutions for the developmentally disabled.
- Hemodialysis patients.
- Recipients of certain blood products.
- Prisoners in long-term correctional facilities.

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	Infant whose mother is not infected with hepatitis B	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, and the third dose must be given at least 2 months after the second and at least 4 months after the first. The third dose should not be given to infants younger than 6 months of age.

All three doses are needed for full and lasting immunity.

Ask your doctor or nurse for more information.

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 *serious* allergic reaction to:

—A previous dose of hepatitis B vaccine, or

—Baker's yeast (the kind used for making bread)

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 life-threatening problems, such as severe allergic reactions. The risk of hepatitis B 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 you 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.dhhs.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. They can give you the Parents Guide to Childhood Immunization, Immunization of Adults: A Call to Action, or other information.
- Contact the Centers for Disease Control and Prevention (CDC):

—Call 1–800–232–2522 (English)
—Call 1–888–443–7232 (English)
—Call 1–800–232–0233 (Español)
—Visit the National Immunization Program's website at http://www.cdc.gov/nip
—Visit the Hepatitis Branch's website at http://www.cdc.gov/ncidod/diseases/hepatitis/hepatitis.htm

U.S. Department of Health & Human Services
Centers for Disease Control and Prevention
National Immunization Program
Hepatitis B (00/00/00) (Proposed)
Vaccine Information Statement
42 U.S.C. § 300aa–26

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Haemophilus Influenzae Type B (HIB) Vaccine—What You Need to Know

1. What is Hib Disease?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by a bacteria. It usually strikes children under 5 years old.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person through the air. If the germs stay in the child's nose and throat, the child probably will not become sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the brain and spinal cord coverings which can lead to lasting brain damage.

In addition to meningitis, Hib disease can cause:

- Hearing loss.
- Pneumonia.
- Severe swelling in the throat, making it hard to breathe.
- Infections of the blood, joints, bones, and covering of the heart.
- Death.

Hib Vaccine Can Prevent Hib Disease

Many more children would get Hib disease if we stopped vaccinating.

2. Who Should Get Hib Vaccine and When?

Children Should Get Hib Vaccine At:

✔ 2 months of age
✔ 4 months of age
✔ 6 months of age*
✔ 12–15 months of age

*Depending on what brand of Hib vaccine is used, your child might not need the dose at 6 months of age. Your doctor or nurse will tell you if this dose is needed.

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.

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

Older Children and Adults

Children over 5 years old usually do not need Hib vaccine. But some older children or adults with special health conditions should get it. These conditions include sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or cancer treatment with drugs. Ask your doctor or nurse for details.

3. Some People Should Not Get Hib Vaccine or Should Wait

People who have ever had a *serious* allergic reaction to a previous dose of Hib vaccine should not get another dose.

Children less than 6 weeks of age should not get Hib vaccine.

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

Ask your doctor or nurse for more information.

4. What Are the Risks From Hib Vaccine?

- A vaccine, like any medicine, is capable of causing life-threatening problems, such as severe allergic reactions. The risk of Hib vaccine causing serious harm, or death, is extremely small.
- Getting Hib vaccine is much safer than getting Hib disease.
- Most people who get Hib vaccine do not have any problems with it.

Mild Problems

- Redness, warmth, or swelling where the shot was given (up to 1 out of 25 children).
- Fever over 101°F (up to 1 out of 20 children).

If these problems happen, they usually start within a day of vaccination. They may last 2–3 days.

5. 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.

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.

6. 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 you 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.dhhs.gov/bhpr/vicp

7. 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. They can give you the Parents Guide to Childhood Immunization or other information.

• 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

U.S. Department of Health & Human Services
Centers for Disease Control and Prevention
National Immunization Program
Hib (00/00/00) (Proposed)
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Chickenpox Vaccine—What You Need to Know

1. Why Get Vaccinated?

Chickenpox (also called *Varicella*) is a Common Childhood Disease

It is usually mild, but it can be serious, especially in young infants and adults.

• The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.

• It causes a rash, itching, fever, and tiredness.

• It can lead to severe skin infection, scars, pneumonia, brain damage, or death.

• A person who has had chickenpox can get a painful rash called shingles years later.

• About 12,000 people are hospitalized for chickenpox each year in the United States.

• About 100 people die each year in the United States as a result of chickenpox.

Chickenpox Vaccine Can Prevent Chickenpox

2. Chickenpox Vaccine

• If someone who has been vaccinated does get chickenpox, it is usually very mild. They have fewer spots, are less likely to have a fever, and will recover faster.

3. Who Should Get Chickenpox Vaccine and When?

• Children should get chickenpox vaccine between 12 and 18 months of age.

• Older children, or adults, who have never had chickenpox or chickenpox vaccine should get the vaccine. It can be given at any age.

Dosage:

Children 1–12 years of age: 1 dose
Anyone 13 years of age or older: 2 doses, 4–8 weeks apart

Ask your doctor or nurse for details.

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

4. Some People Should Not Get Chickenpox Vaccine or Should Wait

• People who have ever had a *serious* allergic reaction to gelatin, the antibiotic neomycin, or a previous dose of chickenpox vaccine should not get the vaccine.

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

• Pregnant women should wait to get chickenpox vaccine until after they have given birth.

• Some people should check with their doctor about whether they should get chickenpox vaccine. These people include anyone who:

—Has HIV/AIDS, or another disease that affects the immune system
—Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer
—Has any kind of cancer
—Is taking cancer treatment with x-rays or drugs

• People who recently had a transfusion or were given other blood products should ask their doctor when they may get chickenpox vaccine.

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

5. What Are the Risks From Chickenpox Vaccine?

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

• Getting chickenpox vaccine is much safer than getting chickenpox disease.

• Most people who get chickenpox vaccine do not have any problems with it.

Mild Problems

• Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults).

• Fever (1 out of 6 children, 1 out of 10 adolescents or adults).

• Mild rash, up to a month after vaccination (up to 1 out of 16 people getting the vaccine). These people can, rarely, spread the vaccine virus to other members of their household.

Moderate Problems

• Seizure (jerking or staring) caused by fever (less than 1 out of 1,000 people getting the vaccine).

Severe Problems

Some severe problems, including pneumonia, brain damage, or low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely 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 it occurs, a high fever or seizure would occur one to six 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 you 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.dhhs.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. They can give you the Parents Guide to Childhood Immunization, Immunization of Adults: A Call to Action, or other information.

• 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
U.S. Department of Health & Human Services
Centers for Disease Control and Prevention
National Immunization Program
Varicella (00/00/00) (Proposed)
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42 U.S.C. § 300aa–26

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Measles, Mumps and Rubella Vaccines—What You Need To Know

1. Why Get Vaccinated?

Measles, Mumps, and Rubella Are Serious Diseases

Measles

• Measles virus causes rash, cough, runny nose, eye irritation, and fever.
• It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

Mumps

• Mumps virus causes fever, headache, and swollen glands.
• It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles, and, rarely, death.

Rubella (German Measles)

• Rubella virus causes rash, mild fever, swollen glands, and arthritis (mostly in women).
• If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

You or your child could catch these diseases by being around someone who has them. They spread from person to person through the air.

Measles, Mumps, and Rubella (MMR) Vaccine Can Prevent These Diseases

Most children who get their MMR shots will not get these diseases. Many more children would get them if we stopped vaccinating.

2. Who Should Get MMR Vaccine and When?

Children should get 2 doses of MMR vaccine, the first at:

√ 12–15 months of age

And the second at:

√ 4–6 years of age

These are the recommended ages. But children can get the second dose of MMR vaccine at any age, as long as it is at least 28 days after the first dose.

Some Adults Should Also Get MMR Vaccine

Generally, anyone 18 years of age or older, who was born after 1957, should get at least one dose of MMR vaccine unless they:

• Have documentation of at least one dose each of measles, mumps, and rubella vaccines,
• Have other acceptable evidence of immunity to these three diseases, or
• Have a medical reason why they should not get the vaccines (see #3, below).

Ask your doctor or nurse for more information.

Adults with a special need for these three vaccines include:

• College students, trade school students, and other students beyond high school.
• People working in hospitals and other medical facilities.
• International travelers and passengers on cruise ships.
• Women of childbearing age (who are not pregnant).
• People who move to the US from countries that do not have routine rubella vaccination.

MMR vaccine may be given at the same time as other vaccines. Immunity from MMR vaccine probably lasts for life.

3. Some People Should Not Get MMR Vaccine or Should Wait

• People who have ever had a *serious* allergic reaction to gelatin, the antibiotic neomycin, or a previous dose of MMR vaccine should not get the vaccine.
• People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMR vaccine.
• Pregnant women should wait to get MMR vaccine until after they have given birth. Women should not get pregnant for 3 months after getting MMR vaccine.
• Some people should check with their doctor about whether they should get MMR vaccine. These people include anyone who:
—Has HIV/AIDS, or another disease that affects the immune system.
—Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
—Has any kind of cancer.
—Is taking cancer treatment with x-rays or drugs.
—Has ever had a low platelet count (a blood disorder).
• People who recently had a transfusion or were given other blood products should ask their doctor when they may get MMR vaccine.

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

4. What Are the Risks From MMR Vaccine?

• A vaccine, like any medicine, is capable of causing life-threatening problems, such as severe allergic reactions. The risk of MMR vaccine causing serious harm, or death, is extremely small.
• Getting MMR vaccine is much safer than getting any of these three diseases.
• Most people who get MMR vaccine do not have any problems with it.

Mild Problems

• Fever (up to 1 person out of 6).
• Mild rash (about 1 person out of 20).
• Swelling of glands in the cheeks, neck, or under the jaw (rare).

If these problems occur, it is usually within 7–12 days after the shot. They occur less often after the second dose.

Moderate Problems

• Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses).
• Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4).
• Low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses).

Severe Problems (Very Rare)

• Serious allergic reaction (less than 1 out of a million doses).

Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:

• Deafness.
• Long seizures, coma, or lowered consciousness.
• Permanent brain damage.

5. 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 it occurs, a high fever or seizure would occur 1 to 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.

6. 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 you 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.dhhs.gov/bhpr/vicp

7. 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. They can give you the Parents Guide to Childhood Immunization, Immunization of Adults: A Call to Action, or other information.

• 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

U.S. Department of Health & Human Services
Centers for Disease Control and Prevention
National Immunization Program
MMR (00/00/00) (Proposed)
Vaccine Information Statement
42 U.S.C. 300aa–26

Dated: August 28, 1998.

Thena M. Durham,

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

[FR Doc. 98–23736 Filed 9–2–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Annual Report on Services Provided (ACF–700).

OMB No.: 0980–0241.

Description: The Child Care and Development Fund (CCDF) Report is the required annual tribal aggregate information on services provided through the CCDF, which is required per Child Care and Development Block Grant (CCDBG) Final Rule 45 CFR Parts 98 and 99. Tribes are required to submit annual aggregate data appropriate to tribal programs on children and families receiving CCDF-funds or CCDBG funded Child care services. The CCDF regulations require Tribal Lead Agencies to report a supplemental narrative which describes general child care activities and actions in the Tribal Lead Agency's service area and is not limited to the CCDF-funded activities but addresses all child care in the Tribal Lead Agency's service area. This information will be included in the Secretary's report to Congress, as appropriate, and will be shared with all Tribal Lead Agencies to inform them of CCDF or CCDBG-funded activities in other tribal programs.

Respondents: Tribal Governments.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Annual Report (ACF–700)	224	1	40	9,760

Estimated Total Annual Burden Hours: 9,760.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF: ACF Reports Clearance Officer.

OMB Comment:

OMB is required to make a decision concerning the collection information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the followin Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Laura Oliven.

Dated: August 28, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–23745 Filed 9–2–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0698]

Agency Information Collection Activities: Proposed Collection; Comment Request; Survey of Consumer Attitudes Toward Potential Changes in Food Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary survey of consumer attitudes toward potential changes in food standards of identity.

DATES: Submit written comments on the collection of information by November 2, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget