Dated: November 4, 2005.

Betsey S. Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–22440 Filed 11–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Vaccine Information Statements for Influenza Vaccines; Revised Instructions for Use of Vaccine Information Statements

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

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (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. On July 28, 2005, CDC published a notice in the **Federal Register** (70 FR 43694) seeking public comments on proposed new vaccine information materials for trivalent influenza vaccines and hepatitis A vaccines. The 60 day comment period ended on September 26, 2005. Following review of the comments submitted and consultation as required under the law, CDC has finalized the influenza vaccine information materials. The final influenza materials, and revised instructions for their use and for use of materials for other covered vaccines, are contained in this notice. The final hepatitis A vaccine information materials will be published later.

DATES: Beginning no later than January 1, 2006, each health care provider who administers any trivalent influenza vaccine to any child or adult in the United States shall provide copies of the relevant vaccine information materials contained in this notice, dated October 20, 2005, in conformance with the November 4, 2005 CDC Instructions for the Use of Vaccine Information Statements, also contained in this notice.

FOR FURTHER INFORMATION CONTACT: Stephen L. Cochi, M.D., M.P.H., Acting 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, also known as Vaccine Information Statements (VIS), 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. In addition, use of vaccine information materials for pneumococcal conjugate vaccine has been required since December 15, 2002.

Instructions for use of the vaccine information materials and copies of the materials can be downloaded in PDF format from the CDC Web site 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).

New Vaccine Information Materials

Inactivated Influenza Vaccine Information Statement; Live, Intranasal Influenza Vaccine Information Statement; Hepatitis A Vaccine Information Statement

Following the addition of hepatitis A and trivalent influenza vaccines to the National Vaccine Injury Compensation Program, CDC, as required under 42 U.S.C. 300aa–26, proposed vaccine information materials covering those vaccines in a **Federal Register** notice published on July 28, 2005 (70 FR 43694). In order to have Influenza Vaccine Information Statements available for voluntary use in the current influenza vaccination season, the proposed influenza vaccine materials were also issued as interim VISs through that notice.

The new vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, the American Academy of Family Physicians, American Academy of Pediatrics, American Medical Association, Emory Vaccine Research Center, Every Child By Two, Immunization Action Coalition and the National PTA. Also, CDC sought consultation with other organizations; however, those organizations did not provide comments.

Following consultation and review of comments submitted, the vaccine information materials covering trivalent influenza vaccines have been finalized and are contained in this notice. These Vaccine Information Statements, dated October 20, 2005, are entitled: ''Inactivated Influenza Vaccine: What You Need to Know'' and ''Live, Intranasal Influenza Vaccine: What You Need to Know.'' CDC has also revised the ''Instructions for the Use of Vaccine Information Statements.'' The vaccine information materials covering hepatitis A vaccine will be finalized and published at a later date.

With publication of this notice, as of January 1, 2006, all health care providers will be required to provide

copies of influenza vaccine information materials prior to immunization in conformance with CDC's November 4, 2005 ''Instructions for the Use of Vaccine Information Statements'' which are contained in this notice.

* * * * *

Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide Vaccine Information Statement (VIS) When Vaccination Is Given

As required under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa–26), all health care providers in the United States who administer to any child or adult any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, Haemophilus influenzae type b (Hib), hepatitis B, trivalent influenza (use of influenza VISs required effective January 1, 2006), pneumococcal conjugate, or varicella (chickenpox) vaccine shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- To the parent or legal representative* of any child to whom the provider intends to administer such vaccine, and
- To any adult to whom the provider intends to administer such vaccine. (In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative.* If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each immunization.)

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

- A Legal representative is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

2. Record information for each VIS provided

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating (1) the edition date of the Vaccine Information Statement distributed and (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. 300aa–25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log): (3) The name, address and title of the individual who administers the vaccine, (4) the date of administration and (5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's Web site at *http://www.cdc.gov/nip/publications/VIS*. Copies are available in English and in other languages.

Edition Dates of Current VISs

Diphtheria, Tetanus, Pertussis (DTaP/DT): July 30, 2001.

Haemophilus influenzae type b (Hib): December 16, 1998.

Hepatitis B: July 11, 2001.

Inactivated Influenza: October 20, 2005.

Live, Intranasal Influenza: October 20, 2005.

Measles, Mumps, Rubella (MMR): January 15, 2003.

Pneumococcal conjugate: September 30, 2002.

Polio: January 1, 2000.

Tetanus Diphtheria (Td): June 10, 1994.

Varicella (chickenpox): December 16, 1998.

Reference 42 U.S.C. 300aa–26: November 4, 2005.

* * * * *

Inactivated Influenza Vaccine Information Statement

Inactivated Influenza Vaccine: What You Need To Know

1. Why get vaccinated?

Influenza (''flu'') is a very contagious disease.

It is caused by the influenza virus, which spreads from infected persons to the nose or throat of others.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza. For most people, it lasts only a few days. It can cause:

- Fever • Sore throat • Chills
- Fatigue • Cough • Headache
- Muscle aches.

Some people get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever and seizures in children. Influenza kills about 36,000 people each year in the United States, mostly among the elderly.

Influenza vaccine can prevent influenza.

2. Inactivated influenza vaccine.

There are two types of influenza vaccine:

An inactivated (killed) vaccine, given as a shot, has been used in the United States for many years.

A live, weakened vaccine was licensed in 2003. It is sprayed into the nostrils. This vaccine is described in a separate Vaccine Information Statement.

Influenza viruses are constantly changing. Therefore, influenza vaccines are updated every year, and an annual vaccination is recommended.

For most people influenza vaccine prevents serious illness caused by the influenza virus. It will not prevent ''influenza-like'' illnesses caused by other viruses.

It takes about 2 weeks for protection to develop after the shot, and protection can last up to a year.

Inactivated influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

Some inactivated influenza vaccine contains thimerosal, a preservative that contains mercury. Some people believe thimerosal may be related to developmental problems in children. In 2004 the Institute of Medicine published a report concluding that, based on scientific studies, there is no evidence of such a relationship. If you are concerned about thimerosal, ask your doctor about thimerosal-free influenza vaccine.

3. Who should get inactivated influenza vaccine?

Influenza vaccine can be given to people 6 months of age and older. It is recommended for people who are at risk of serious influenza or its complications, and for people who can spread influenza to those at high risk (including all household members):

People at high risk for complications from influenza:

- All children 6–23 months of age.

• People 65 years of age and older.
• Residents of long-term care facilities housing persons with chronic medical conditions.
• People who have long-term health problems with:
—Heart disease
—Lung disease
—Asthma
—Kidney disease
—Metabolic disease, such as diabetes
—Anemia, and other blood disorders
• People with certain muscle or nerve disorders (such as seizure disorders or severe cerebral palsy) that can lead to breathing or swallowing problems.
• People with a weakened immune system due to:
—HIV/AIDS or other diseases affecting the immune system.
—Long-term treatment with drugs such as steroids.
—Cancer treatment with x-rays or drugs.
• People 6 months to 18 years of age on long-term aspirin treatment (these people could develop Reye Syndrome if they got influenza).
• Women who will be pregnant during influenza season.

People who can spread influenza to those at high risk:

• Household contacts and out-of-home caretakers of infants from 0–23 months of age.
• Physicians, nurses, family members, or anyone else in close contact with people at risk of serious influenza.

Influenza vaccine is also recommended for adults 50–64 years of age and anyone else who wants to reduce their chance of catching influenza.

An annual flu shot should be considered for:

• People who provide essential community services.
• People living in dormitories or under other crowded conditions, to prevent outbreaks.
• People at high risk of influenza complications who travel to the Southern hemisphere between April and September, or to the tropics or in organized tourist groups at any time.

4. When should I get influenza vaccine?

The best time to get influenza vaccine is in October or November.

Influenza season usually peaks in February, but it can peak any time from November through May. So getting the vaccine in December, or even later, can be beneficial in most years.

Some people should get their flu shot in October or earlier:

—People 50 years of age and older,
—Younger people at high risk from influenza and its complications (including children 6 through 23 months of age),
—Household contacts of people at high risk,
—Healthcare workers, and
—Children younger than 9 years of age getting influenza vaccine for the first time.

Most people need one flu shot each year. Children younger than 9 years of age getting influenza vaccine for the first time should get 2 doses, given at least one month apart.

5. Some people should talk with a doctor before getting influenza vaccine.

Some people should not get inactivated influenza vaccine or should wait before getting it.

• Tell your doctor if you have any severe (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.
—Influenza vaccine virus is grown in eggs. People with a severe egg allergy should not get the vaccine.
—A severe allergy to any vaccine component is also a reason to not get the vaccine.
—If you have had a severe reaction after a previous dose of influenza vaccine, tell your doctor.
• Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). You may be able to get the vaccine, but your doctor should help you make the decision.
• People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

6. What are the risks from inactivated influenza vaccine?

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

Serious problems from influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

• Soreness, redness, or swelling where the shot was given.
• Fever.
• Aches.

If these problems occur, they usually begin soon after the shot and last 1–2 days.

Severe problems:

• Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is within a few minutes to a few hours after the shot.
• In 1976, a certain type of influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

7. What if there is a severe reaction?

What should I look for?

• Any unusual condition, such as a 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 report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS Web site at *http://www.vaers.hhs.gov*, or by calling 1–800–822–7967. VAERS does not provide medical advice.

8. The National Vaccine Injury Compensation Program

In the 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 Web site at *http://www.hrsa.gov/osp/vicp*.

9. How can I learn more?

• Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
—Call 1–800–232–4636 (1–800–CDC–INFO)
—Visit CDC's Web site at *http://www.cdc.gov/flu*.
—Vaccine Information Statement.
—(October 20, 2005) Inactivated Influenza Vaccine.

42 U.S.C. 300aa–26.

Department of Health and Human Services, Centers for Disease Control

and Prevention, National Immunization Program.

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Live, Intranasal Influenza Vaccine Information Statement

Live Intranasal Influenza Vaccine: What You Need to Know

1. Why get vaccinated?

Influenza (''flu'') is a very contagious disease.

It is caused by the influenza virus, which spreads from infected persons to the nose or throat of others.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days. It can cause:

- Fever
- Sore throat
- Chills
- Fatigue
- Cough
- Headache
- Muscle aches

Some people get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever and seizures in children. Influenza kills about 36,000 people each year in the United States.

Influenza vaccine can prevent influenza.

2. Live, attenuated influenza vaccine (nasal spray)

There are two types of influenza vaccine:

Live, attenuated influenza vaccine (LAIV) was licensed in 2003. LAIV contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils rather than injected into the muscle. It is recommended for healthy children and adults from 5 through 49 years of age, who are not pregnant.

Inactivated influenza vaccine, sometimes called the ''flu shot,'' has been used for many years and is given by injection. This vaccine is described in a separate Vaccine Information Statement.

Influenza viruses are constantly changing. Therefore, influenza vaccines are updated every year, and annual vaccination is recommended.

For most people influenza vaccine prevents serious illness caused by the influenza virus. It will not prevent ''influenza-like'' illnesses caused by other viruses.

It takes about 2 weeks for protection to develop after vaccination, and protection can last up to a year.

3. Who can get LAIV?

Live, intranasal influenza vaccine is approved for healthy children and adults from 5 through 49 years of age, including those who can spread influenza to people at high risk, such as:

- Household contacts and out-of-home caretakers of infants from 0–23 months of age.
- Physicians and nurses, and family members or anyone else in close contact with people at risk of serious influenza.

Influenza vaccine is also recommended for anyone else who wants to reduce their chance of catching influenza.

LAIV may be considered for:

- People who provide essential community services.
- People living in dormitories or under other crowded conditions, to prevent outbreaks.

4. Who should not get LAIV?

LAIV is not licensed for everyone. The following people should check with their health-care provider about getting the inactivated vaccine:

- Adults 50 years of age or older or children younger than 5.
- People who have long-term health problems with:

—Heart disease
—Lung disease
—Asthma
—Kidney disease
—Metabolic disease, such as diabetes
—Anemia, and other blood disorders

- People with a weakened immune system.
- Children or adolescents on long-term aspirin treatment.
- Pregnant women.
- Anyone with a history of Guillain-Barré syndrome (a severe paralytic illness, also called GBS).

Inactivated influenza vaccine (the flu shot) is the preferred vaccine for people (including health-care workers and family members) coming in close contact with anyone who has a severely weakened immune system (that is, anyone who requires care in a protected environment).

Some people should talk with a doctor before getting either influenza vaccine:

- Anyone who has ever had a serious allergic reaction to eggs or to a previous dose of influenza vaccine.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5. When should I get influenza vaccine?

The best time to get influenza vaccine is in October or November, but LAIV may be given as soon as it is available. Influenza season usually peaks in February, but it can peak any time from November through May. So getting the vaccine in December, or even later, can be beneficial in most years.

Most people need one dose of influenza vaccine each year. Children younger than 9 years of age getting influenza vaccine for the first time should get 2 doses For LAIV, these doses should be given 6–10 weeks apart.

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

6. What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 5–17 years of age have reported mild reactions, including:

- Runny nose, nasal congestion or cough.
- Headache and muscle aches.
- Fever.
- Abdominal pain or occasional vomiting or diarrhea.

Some adults 18–49 years of age have reported:

- Runny nose or nasal congestion.
- Sore throat.
- Cough, chills, tiredness/weakness.
- Headache.

These symptoms did not last long and went away on their own. Although they can occur after vaccination, they may not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Over two million doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

7. What if there is a severe reaction?

What should I look for?

• Any unusual condition, such as a 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 report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS Web site at *http://www.vaers.hhs.gov,* or by calling 1–800–822–7967.

VAERS does not provide medical advice.

8. The National Vaccine Injury Compensation Program

In the 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 Web site at *http://www.hrsa.gov/osp/vicp.*

9. How can I learn more?

• Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.

• Call your local or state health department.

• Contact the Centers for Disease Control and Prevention (CDC):

—Call 1–800–232–4636 (1–800–CDC–INFO).

—Visit CDC's Web site at *http://www.cdc.gov/flu.*

—Vaccine Information Statement.

—Live, Attenuated Influenza Vaccine.

(October 20, 2005)

42 U.S.C. 300aa–26.

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

Dated: November 4, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 05–22441 Filed 11–9–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0281]

Medical Devices: A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.'' The revised guidance extends the voluntary pilot premarket review program Summary Technical Documentation (STED pilot) until we have received an adequate number of submissions to evaluate the STED pilot. The pilot program is intended for evaluating the utility of an alternative submission procedure.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–4879, or Kenneth J. Cavanaugh Jr., Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 26, 2003 (68 FR 38068), FDA announced the availability of a guidance document entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.'' The guidance document announced a pilot program for a premarket review program and encouraged participation from the medical device industry. The pilot program is intended to evaluate the utility of an alternative submission procedure as described in the draft STED document prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). The document seeks to harmonize the different requirements for premarket submissions in various countries.

The June 26, 2003, guidance and notice of availability announced that the pilot program would be in effect for 1 year from the date of publication of the notice of availability. In the **Federal Register** of July 23, 2004 (69 FR 44040), the pilot program was subsequently extended until June 25, 2005. FDA has received no comments on the guidance issued on June 26, 2003, or the updated version published on July 23, 2004. In this revised guidance, FDA is extending the pilot program until we have received a sufficient number of submissions to evaluate the pilot program. In addition, FDA is updating the contact information and the references to the GHTF documents, along with other minor editorial changes. The FDA guidance document is intended to assist the medical device industry in making submissions to FDA that use a proposed internationally harmonized format and content for premarket submissions, e.g., premarket approval applications and 510(k) submissions in the United States. The revised guidance is a level 2 guidance under FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). FDA made the guidance available on its Web site at *http://www.fda.gov/cdrh/ode/guidance/1347.html.*

The GHTF is a voluntary group comprised of medical device regulatory officials and industry representatives from the United States, Canada, Australia, the European Union, and Japan. The goals of the GHTF include the following items: (1) Encourage convergence in regulatory practices with respect to ensuring the safety, effectiveness, performance, and quality