assistance to patients, doctors, and the general public.

The ICA has over 20 years of achievement unmatched by any other health organization dealing with IC issues. Some of these achievements include:

• Public awareness—the ICA has consistently attracted media attention to IC. Numerous articles featuring IC and the ICA have been published from the ''New York Times,'' ''SELF Magazine,'' ''Good Housekeeping,'' and many other national magazines. Subject-matter experts from the ICA have appeared on national TV and radio programs to include ABC's ''Good Morning America,'' CNN, and National Public Radio.

• Physician and Patient Education—Subject-matter experts from the ICA have published numerous articles on IC for professional journals including ''Urology'' and the ''World Journal of Urology.'' The ICA has worked closely with the NIDDK Division of Urology for over 15 years and has co-sponsored with the NIDDK, international scientific conferences as well as national IC patient meetings on IC biannually. ICA has also sponsored numerous regional educational programs for patients throughout the United States each year.

• Patient Support—The ICA provides a toll-free 800 number designed to quickly assist both IC patients and healthcare providers. ICA also provides nationwide individual support via telephone and e-mail by ICA National Patient Support Advocates; the International IC Question Corner on its Web site, where patients can e-mail the ICA and receive one-on-one assistance with their questions; the ICA Physician Registry which helps IC patients find IC-knowledgeable physicians; and IC connections, which brings together patients based on specific interests, concerns and regions, and an informational program on how to start new IC support groups.

• Innovative resources—the ICA published, and continues to regularly update, a series of brochures and fact sheets as well as ''IC Treatment Guidelines''—the *first* comprehensive summary of IC treatments and medications designed for patients and their physicians for use as the basis for an individualized treatment plan. The ICA also publishes an on-line monthly news digest, ''Café ICA,'' and two quarterly newsletters—the ''ICA Update,'' the only printed newsletter on IC in the United States, and the ''ICA Physician Perspectives.'' ICA also publishes a ''Pocket Guide'' series for continuing patient education.

• Comprehensive Web Site—The ICA's Web site *http://www.icahelp.org*, established in 1995, is the most comprehensive Web site on IC available today, receiving over 1.4 million hits per month. The site includes: a Clinical trials section, their on-line monthly news digest—''Café ICA,'' IC Question Corner which provides one-on-one patient support, Treatment Options, a section for health care providers, a comprehensive research section, and much more * * *.

• Non-profit leadership—the ICA remains the *only* United States 501 (c)(3) registered non-profit organization to fund IC research and provide educational programs on IC for both physicians and patients, as well as the public at large.

This mission and ICA's extensive network of resources and record of unmatched achievements over the last 20 years, makes it highly probable that ICA will successfully implement and complete all the required activities for this program announcement. For these reasons, the ICA is the only organization being considered for this program announcement.

C. Funding

Approximately $ 510,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before September 1, 2005, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146; telephone: 770–488–2700.

For technical questions about this program, contact: Richard S. Roman, Project Officer, HCAS/DACH/NCCDPHP/CDC, 4770 Buford Hwy., N.E., MS K–51, Chamblee, GA 30341; telephone: 770–488–5144; e-mail: *rsr1@cdc.gov.*

Dated: July 22, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–14927 Filed 7–27–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention

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

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.–4:30 p.m., August 25, 2005.

Place: Emory Conference Center, 1615 Clifton Road, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

Matters to Be Discussed: Agenda items will include updates on CDC priorities with discussions of program activities including updates on CDC scientific and programmatic activities, strategic imperatives, goals, research agenda, and health equity.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Robert Delaney, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–14, Atlanta, Georgia 30333. Telephone (404) 639–7000.

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

Dated: July 25, 2005.

Diane Allen,

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

[FR Doc. 05–15019 Filed 7–27–05; 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 Hepatitis A and Influenza Vaccines; Interim Vaccine Information Materials for Influenza 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 (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. CDC seeks written comment on proposed new vaccine information materials for hepatitis A and trivalent influenza vaccines. In addition, to ensure that influenza vaccine information materials are available at the beginning of the upcoming influenza vaccination season, this notice includes interim vaccine information materials covering influenza vaccines for use pending issuance of final influenza materials following completion of the formal NCVIA development process.

DATES: Written comments are invited and must be received on or before September 26, 2005.

ADDRESSES: Written comments should be addressed to 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, N.E., Atlanta, Georgia 30333.

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, N.E., 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 found on 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).

Proposed Hepatitis A Vaccine Information Materials

Interim and Proposed Influenza Vaccine Information Materials

With the December 1, 2004 addition of hepatitis A vaccine and the July 1, 2005 addition of trivalent influenza vaccines to the National Vaccine Injury Compensation Program, CDC, as required under 42 U.S.C. 300aa–26, is proposing vaccine information materials covering those vaccines, which are included in this notice. In addition, in order to have Influenza Vaccine Information Statements available for use in the upcoming influenza vaccination season, the proposed influenza vaccine materials are also being issued as interim VISs through this notice. These interim materials may be used by providers pending completion of the final influenza vaccine information materials.

Development of Vaccine Information Materials

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

In addition, we invite written comment on the proposed vaccine information materials that follow, entitled ''Hepatitis A Vaccine: What You Need to Know,'' ''Inactivated Influenza Vaccine: What You Need to Know,'' and ''Live, Intranasal Influenza 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 mandatory use.

We also propose to revise the January 15, 2003 Instructions for the Use of Vaccine Information Statements to add the requirement for use of the hepatitis A and influenza vaccine information materials.

Use of Interim Influenza Vaccine Information Materials

The proposed influenza vaccine information materials included in this notice are concurrently being issued through this notice as interim Influenza Vaccine Information Statements, dated July 18, 2005. Providers are encouraged to use these interim materials pending issuance of the final influenza materials following completion of the formal NCVIA development process. Copies of these interim influenza VISs can be downloaded in PDF format from the CDC Web site at: *http://www.cdc.gov/nip/publications/VIS/*.

Proposed Hepatitis A Vaccine Information Statement

Hepatitis A Vaccine: What You Need to Know

1. Why get vaccinated?

Hepatitis A is a serious liver disease caused by the hepatitis A virus (HAV). HAV is found in the stool of people with hepatitis A. It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV.

Hepatitis A can cause:

- Mild ''flu-like'' illness;
- Jaundice (yellow skin or eyes);
- Severe stomach pains and diarrhea.

People who become ill with hepatitis A often have to be hospitalized.

About 100 people die from hepatitis A infection in the U.S. each year.

A person who has hepatitis A can easily pass the disease to other people in the same household. Hepatitis A vaccine can prevent hepatitis A.

2. Who should get hepatitis A vaccine and when?

WHO?

- Children and adolescents who live in states or communities where routine vaccination has been recommended.
- People 2 years of age and older traveling to or working in countries where risk for catching hepatitis A is high. These include countries located in Central or South America, the Caribbean, Mexico, Asia (except Japan), Africa, and Eastern Europe.
- Men who have sex with men.
- People who use street drugs.
- People with chronic liver disease.
- People who are treated with clotting factor concentrates.
- People who work with HAV-infected primates or who work with HAV in research laboratories.

Other people might get hepatitis A vaccine in special situations:

- Hepatitis A vaccine might be recommended for children or adolescents in communities where outbreaks of hepatitis A are occurring.

Hepatitis A vaccine is not licensed for children younger than 2 years of age.

WHEN?

Two doses of the vaccine are needed for lasting protection. These doses should be given at least 6 months apart. If you miss the second dose, get it as soon as you can. There is no need to start over.

—The hepatitis A vaccine series may be started whenever a person is at risk of infection.
—For travelers, the vaccine works best if given at least one month before traveling.
—Travelers who get the vaccine less than one month before traveling may also get a second shot called Immune Globulin (IG). IG gives immediate, temporary protection.

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

3. Some people should not get hepatitis A vaccine or should wait

- Anyone who has ever had a severe (life-threatening) allergic reaction to a previous dose of hepatitis A vaccine should not get another dose.
- Anyone who has a severe (life-threatening) allergy to any vaccine component should not get the vaccine. Tell your doctor if you have any severe allergies.
- People who are moderately or severely ill should usually wait until they recover before getting hepatitis A 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.
- Tell your doctor if you are pregnant. The safety of hepatitis A vaccine for pregnant women has not been determined. But there is no evidence that it is harmful to either pregnant women or their unborn babies. The risk, if any, is believed to be very low.

4. What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small. Getting hepatitis A vaccine is much safer than getting the disease.

Mild problems:

- Soreness where the shot was given (about 1 out of 2 adults and up to 1 out of 5 children);
- Headache (about 1 out of 6 adults and 1 out of 20 children);
- Loss of appetite (about 1 out of 12 children);
- Tiredness (about 1 out of 14 adults).

If these problems occur, they usually last for 1 or 2 days.

Severe problems:

- Serious allergic reaction, within a few minutes to a few hours of the shot (very rare).

5. 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.

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 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 Web site at *http://www.hrsa.gov/osp/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.
- Contact the Centers for Disease Control and Prevention (CDC):

—Call 1–800–232–4636 (1–800–CDC–INFO)
—Visit CDC Web sites at: *http://www.cdc.gov/hepatitis* or *http://www.cdc.gov/nip.*

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

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

Interim and Proposed 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;
—Kidney disease;
—Lung disease;
—Metabolic disease, such as diabetes;
—Asthma;
—Anemia, and other blood disorders.

- People with certain conditions (such as neuromuscular disorders) that can cause breathing 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 flu 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.*

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

Vaccine Information Statement, Inactivated Influenza Vaccine, (6/18/05) (Interim), 42 U.S.C. 300aa–26.

Interim and Proposed 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 most healthcare workers and household contacts of most people at high risk for influenza complications. However, LAIV should not be given to pregnant women or people with certain medical conditions.

4. Who should not get LAIV?

The following people should not get live intranasal influenza vaccine. They 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;
—Kidney disease;
—Lung disease;
—Metabolic disease, such as diabetes;
—Asthma;
—Anemia, and other blood disorders.

• People with a weakened immune system due to:

—HIV/AIDS or other diseases affecting the immune system;
—Long-term treatment with drugs that weaken the immune system, such as steroids;
—Cancer treatment with x-rays or drugs.

• Children or adolescents on long-term aspirin treatment (these people could develop Reye syndrome if they get influenza).

• 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. 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. This includes other live vaccines, such as MMR or chickenpox. But if two live vaccines are not given on the same day, they should be given at least 4 weeks apart.

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 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.*

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

Vaccine Information Statement, Live, Intranasal Influenza Vaccine, (6/18/05) (Interim), 42 U.S.C. 300aa–26.

Dated: July 22, 2005.

James D. Seligman,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N–0510]

Thomas M. Rodgers, Jr.; Denial of Hearing; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Mr. Thomas M. Rodgers, Jr.'s request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Mr. Thomas M. Rodgers, Jr., for 5 years from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Mr. Rodgers was convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the act, and that the type of conduct that served as the basis for the convictions undermines the process for the regulation of drugs. Mr. Rodgers failed to file with FDA information and analyses sufficient to create a basis for a hearing concerning this action. Therefore, FDA finds that there is no genuine and substantial issue of fact to grant a hearing on the debarment.

DATES: This order is effective July 28, 2005.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

On May 4, 2000, the U.S. District Court for the District of Massachusetts accepted a plea of guilty from Mr. Thomas M. Rodgers, Jr. for three counts charged as Federal misdemeanors under section 303(a)(1) of the act (21 U.S.C. 333(a)(1)): (1) Owning and operating an unregistered facility for the manufacture of drugs (301(p) of the act (21 U.S.C. 331(p))); (2) shipping an unapproved new drug in interstate commerce (301(d) of the act; and (3) shipping an adulterated drug in interstate commerce (301(a) of the act).Mr. Rodgers was the Chairman of the Board of Directors and majority shareholder of Private Biologicals Corporation (PBC). PBC, which was not registered as an establishment engaged in the manufacture of drugs, was in the business of producing a product identified as ''LK–200,'' an unapproved new drug which PBC and its agents intended to be used in the treatment of a variety of diseases, including various forms of cancer. Mr. Rodgers caused LK–200, an unapproved and adulterated new drug, to be introduced into interstate commerce.

As a result of Mr. Rodgers' conviction, FDA sent to Mr. Rodgers by certified letter on December 17, 2002, a proposal to debar Mr. Rodgers for 5 years from providing services in any capacity to a person that has an approved or pending drug product application, including but not limited to, a biologics license application. The letter also provided Mr. Rodgers notice of an opportunity for a hearing on the proposal in accordance