• 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]

BILLING CODE 4163–18–P

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

of medical devices; (2) promote technological innovation; and (3) facilitate international trade. GHTF provides further information concerning the structure, goals, and procedures at the GHTF Web site and can be accessed at *http://ghtf.org*.

II. Significance of Guidance

This guidance is being issued consistent with FDA's Good Guidance Practice (GGP) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the GHTF recommendations as related to premarket submission to FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive a copy of ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff,'' by fax call CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign #. Follow the remaining voice prompts to complete your request.

To receive ''A Pilot Program to Evaluate a Proposed Globally Harmonised Alternative for Premarket Procedures; Guidance for Industry and FDA Staff,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *gwa@cdrh.fda.gov* to receive a hard copy or an electronic copy. Please use the document number 1347 to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes: Device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's, information on video conferencing, and electronic submissions, Mammography Matters, and other device-related information. The CDRH web site home page may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–22387 Filed 11–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name/address	Effective date
PROGRAM-RELATED CONVICTIONS	
ADAIR, KARISTA LEWISBURG, TN	11/20/2005
AUSTIN, HOWARD OAKDALE, LA	11/20/2005
BAILEY, LAWRENCE SHREVEPORT, LA	11/20/2005
BESAW NALEN, KIMBERLY MANCHESTER, NH	11/20/2005
BLACK, ANTONIA FLINT, TX	11/20/2005
CONVENIENT DENTAL CARE CENTER, PC OKEMOS, MI	11/20/2005
DE LA CRUZ, ALFONSO LOS ANGELES, CA	11/20/2005
ERLICH, RUSSELL BROOKLYN, NY	11/20/2005
FLORES, SILVIA ONTARIO, CA	11/20/2005
GARCIA, ROSEMARIE SAN DIEGO, CA	11/20/2005
HAMILTON BENNETT, MAISHA CHICAGO, IL	11/20/2005
HAWKINS, KIMBERLY SHAKOPEE, MN	11/20/2005
HERNANDEZ, KAREN OKLAHOMA CITY, OK	11/20/2005
KATZ, RONALD OTISVILLE, NY	11/20/2005
KEMMETT, BARBARA BRIDGEWATER, MA	11/20/2005
KUBRICKY, MARK OGDEN, UT	11/20/2005
LAKHTER, ALEXANDER E STROUDSBURG, PA	11/20/2005
LEBEL, ALEXANDER BROOKLYN, NY	11/20/2005
LEEDS, LORI SHAKOPEE, MN	11/20/2005
LITTLE, MARK ANTHONY, TX	11/20/2005
MALVAREZ, NORBERTO MIAMI, FL	11/20/2005
MARTINEZ, CESAR MIAMI, FL	11/20/2005
MORAN, PAT WICHITA FALLS, TX	11/20/2005
SHUMATE, TAMMY LOUISVILLE, KY	11/20/2005
UTUK, BECALO BRYAN, TX	11/20/2005
VU, PHOUA SAN DIEGO, CA	11/20/2005
WALLACE, SHIRLEY JONESBORO, AR	11/20/2005
WILLIAMS-WRIGHT, MYRA MIAMI, FL	11/20/2005
FELONY CONVICTION FOR HEALTH CARE FRAUD	
CHAVEZ, WILLIAM MIAMI, FL	11/20/2005
GONZALEZ, DUVIEL MIAMI, FL	11/20/2005
GORRIN, EDDY MIAMI, FL	11/20/2005
KRZYS, PENNY	11/20/2005