Submit electronic comments to either*http://www.fda.gov/dockets/ecomments* or*http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Sharon Lappalainen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4095, or by e-mail at *Sharon.Lappalainen@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of February 5, 1980 (45 FR 7926), FDA issued a final rule classifying the electrocardiograph electrode into class II, under the Federal Food, Drug, and Cosmetic Act (the act). An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. FDA has now developed a draft guidance document for the device and, under the act's provisions, is proposing to designate the draft guidance as the special control that, when combined with the general controls, the agency believes will provide a reasonable assurance of the safety and effectiveness of this device type.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate this draft guidance document as the special control for this device and would exempt the device from premarket notification requirements, subject to limitations in 21 CFR 870.9, if the device addresses the issues identified in the special controls guidance by following the draft guidance's recommendations.

The draft special controls guidance document identifies the classification, product code, and classification identification for the electrocardiograph electrode device. In addition, the draft guidance document identifies the risks to health and serves as a special control that, when followed and combined with the general controls, will generally address the risks associated with this generic device type and permit introduction of the device to the market.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the device. 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, regulations, or both.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1597) to identify the guidance you are requesting.

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 assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

## V. 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 paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 26, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E7–19578 Filed 10–3–07; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0348]**

### Establishing a Docket for the Development of Safety and Effectiveness Assessments of Vaccines Used for Pandemic Influenza; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments from manufacturers of vaccines and other interested persons concerning the development of safety and effectiveness assessments of vaccines used for pandemic influenza. FDA is interested in obtaining comments and information to aid in the development of programs for adverse events surveillance following administration of pandemic influenza vaccines, and in the development of protocols to study effectiveness of influenza vaccines in pre-pandemic and pandemic situations.

**DATES:** Submit written or electronic comments on the safety and effectiveness assessments of vaccines for pandemic influenza use, and comments on information submitted to the docket by other interested persons by December 3, 2007.

**ADDRESSES:** Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–1448. Submit electronic comments or information to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr. 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

The National Strategy for Pandemic Influenza was issued by President Bush in November 2005. This National Strategy identifies the U.S. Department of Health and Human Services (HHS) as the lead for medical response and is intended to guide our nation's preparedness and response to pandemic influenza.

The Implementation Plan for the National Strategy for Pandemic Influenza (the Implementation Plan) was issued by the President on May 3, 2006. The Implementation Plan translates the Strategy into more than 300 actions for Federal departments and agencies and sets expectations for State and local governments and other non-Federal entities. FDA's Center for Biologics Evaluation and Research is the lead for the vaccine action items under section 6.1.13.9 parts (1) and (3) of chapter 6 of the Implementation Plan. This section, in part, states that HHS, in coordination with the Department of Defense, the Veteran's Administration, and in collaboration with State, territorial, tribal, and local partners, shall develop and refine mechanisms to: (1) Track adverse events following vaccine and antiviral administration; and (2) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic, within 18 months.

FDA conveyed in our May 31, 2007, Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines (72 FR 30599), that all sponsors who seek licensure of a pandemic influenza vaccine should expect FDA to seek their involvement in working with FDA and other governmental agencies on plans to collect additional safety and effectiveness data, such as through epidemiological studies, when the vaccine is used (see *http://www.fda.gov/cber/gdlns/panfluvac.htm*). FDA and the Centers for Disease Control and Prevention are engaged in discussions about adverse events surveillance during early use of influenza vaccines for pre-pandemic and pandemic situations. Relevant to the actions outlined in the preceding paragraph, we are inviting vaccine manufacturers who are pursuing the development of pre-pandemic and pandemic influenza vaccines, as well as other interested persons, to provide comments and information concerning mechanisms to track adverse events following vaccination, and the development of protocols to study effectiveness of influenza vaccines during a pandemic.

Specifically, we are requesting information on the design of potential studies to assess the effectiveness of influenza vaccine in a pandemic situation, including comments on the potential usefulness of randomized trials, case control studies, or additional study designs, as well as, potential endpoints. In addition, we are seeking comments on organizations and entities, such as managed care organizations, or other public or private entities that may be able to partner with manufacturers and sponsors to assess safety and effectiveness.

We are requesting comments and information to help us understand the complex issues encountered in trying to obtain these data during a pandemic. Your comments and information might assist us in the development of additional guidance documents for the conduct of postmarketing safety surveillance and effectiveness studies for pandemic influenza vaccines.

## II. Comments

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

## III. Electronic Access

Persons with access to the Internet may obtain the National Strategy for Pandemic Influenza, issued November 2005, and the Implementation Plan for the National Strategy, issued May 3, 2006, at (*http://www.pandemicflu.gov/plan/federal/index.html*).

Dated: September 27, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–19577 Filed 10–3–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: HRSA AIDS Drug Assistance Program Quarterly Report—(OMB No. 0915–0294): Revision**

HRSA's AIDS Drug Assistance Program (ADAP) is funded through Part B of Title XXVI of the Public Health Service Act, the Ryan White HIV/AIDS Program, which provides grants to States and Territories. The ADAP provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 States, the District of Columbia, Puerto Rico, and several Territories receive ADAP grants. As part of the funding requirements, ADAP grantees submit quarterly reports that include information on patients served, pharmaceuticals prescribed, pricing, and other sources of support to provide AIDS medication treatment, eligibility