covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The cooperative agreement ensures FDA's participation and leadership in important international risk assessment and standard setting activities for food ingredients, contaminants, and veterinary drug residues. The development of such international standards provides the public with greater assurance of the quality and safety of food sold in the United States.

II. Eligibility Information

Competition is limited to the WHO/IPCS because it is the parent organization of the Joint Food and Agriculture Organization (FAO)/WHO Expert Committee on Food Additives (JECFA), which provides scientific advice to the Codex Alimentarius Commission (CAC). The international food standards established by the CAC are recognized by the World Trade Organization (WTO) as necessary to protect public health and presumed to be consistent with the Sanitary and Phytosanitary (SPS) Agreement of the General Agreement on Tariffs and Trade (GATT). These programs under the IPCS are the only such programs in existence, and make the IPCS unique as a participant in international standard setting for food ingredients, contaminants, and veterinary drug residues. Awarding this cooperative agreement will help ensure that the risk assessments provided by the JECFA to the CAC are science-based, enhance the safety of food sold in the United States, and enhance the safety of food additives and veterinary drug residues in imported food.

As of October 1, 2003, applicants are required to have a Dun and Bradstreet Number (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, foreign applicants should go to *http://www.grants.gov/RequestaDUNS*, 4th paragraph. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

III. Application and Submission

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.gov* or *cpolit@oc.fda.gov*. This RFA can also be viewed on *Grants.gov* under ''Grant Find.'' A copy of the complete RFA can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at *http://www.cfsan.fda.gov/list.html*.

Dated: April 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7288 Filed 4–11–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0182]

Guidance for Industry and Food and Drug Administration Staff; Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled ''Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product.'' The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) delegates to the Office of Combination Products (OCP) responsibility for resolving disputes about the timeliness of premarket review of combination products. This guidance document provides information about presenting requests for resolution of disputes about the timeliness of premarket review of combination products.

DATES: Submit written or electronic comments on agency guidances at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance document to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments concerning the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne O'Shea, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934, FAX: 301–427–1935.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product.'' In the **Federal Register** of May 4, 2004 (69 FR 24653), FDA issued a notice of availability of a draft guidance document covering the same topic. The draft guidance document was entitled ''Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance.''

MDUFMA delegated to OCP responsibility for resolving disputes about the timeliness of reviews of premarket applications covering combination products. This guidance document provides information on how an applicant submitting an application covering a combination product can submit a request that OCP resolve such a dispute.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on how to present to OCP disputes pertaining to the timeliness of reviews of combination products. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments on the guidance at any time. Submit 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Additional copies of this guidance are available at *http://www.fda.gov/oc/combination* or *http://www.fda.gov/ohrms/dockets/default.htm*. You may also request additional copies of the guidance by e-mailing *combination@fda.gov*.

Dated: April 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7265 Filed 4–11–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Addition of Trivalent Influenza Vaccines to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Through this notice, the Secretary announces that trivalent influenza vaccines are covered vaccines under the National Vaccine Injury Compensation Program (VICP), which provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. This notice serves to include trivalent influenza vaccines as covered vaccines under Category XIV (new vaccines) of the Vaccine Injury Table (Table), which lists the vaccines covered under the VICP. This notice ensures that petitioners may file petitions relating to trivalent influenza vaccines with the VICP even before such vaccines are added as a separate and distinct category to the Table through rulemaking.

DATES: This Notice is effective on April 12, 2005. As described below, trivalent influenza vaccines will be covered under the VICP on July 1, 2005.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Medical Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–4198.

SUPPLEMENTARY INFORMATION: The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) to the Secretary for routine administration to children. See section 2114(e)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included as covered vaccines in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines (42 CFR 100.3(c)(5)).

The two prerequisites for adding trivalent influenza vaccines to the VICP as covered vaccines as well as to the Table have been satisfied. In its May 28, 2004, issue of the Morbidity and Mortality Weekly Report, the CDC published its recommendation that influenza vaccines be routinely administered to children between 6 and 23 months of age because children in this age group are at an increased risk for complications from influenza. In addition, on October 22, 2004, the excise tax for trivalent influenza vaccines was enacted by Public Law 108–357, the ''American Jobs Creation Act of 2004 (the Act).'' Section 890 of this Act adds all trivalent vaccines against influenza to section 4132(a)(1) of the Internal Revenue Code of 1986, which defines all taxable vaccines.

By way of background, two types of influenza vaccines are routinely given to millions of individuals in the United States each year. One is an inactivated (killed) virus vaccine administered using a syringe, while the other is a live, attenuated product administered in a nasal spray. Both vaccine types are trivalent, meaning that they each contain three vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season. While trivalent vaccines are commonly used for yearly influenza vaccine campaigns, a monovalent product may sometimes be used if it appears that one strain has the potential to cause widespread disease. Such was the case in 1976–1977 when Swine flu influenza virus was thought to have potential to cause a worldwide pandemic. Bivalent influenza vaccines have also been used in the past, although infrequently. This notice only covers trivalent influenza vaccines.

Under the regulations governing the VICP, Category XIV of the Table specifies that ''[a]ny new vaccine recommended by the [CDC] for routine administration to children, after publication by the Secretary of a notice of coverage'' is a covered vaccine under the Table (42 CFR 100.3(a), Item XIV). As explained above, the CDC's recommendation has been accepted. This Notice serves to satisfy the regulation's publication requirement. Through this notice, trivalent influenza vaccines are included as covered vaccines under Category XIV of the Table. Because the excise tax enacted with respect to influenza vaccines extends only to trivalent vaccines, any non-trivalent influenza vaccines (should they be administered to the public in the future) will not be covered under the VICP or the Table. To the Secretary's knowledge, the only influenza vaccines that have been administered in the United States in the past 8 years are trivalent influenza vaccines.

Under section 2114(e) of the PHS Act, as amended by section 13632(a) of the Omnibus Budget Reconciliation Act of 1993, coverage for a vaccine recommended by the CDC for routine administration to children shall take effect upon the effective date of the tax enacted to provide funds for compensation with respect to the vaccine included as a covered vaccine in the Table. Under section 890 of the American Jobs Creation Act of 2004, the effective date for the excise tax enacted for trivalent vaccines against influenza applies on and after the later of: ''(A) the first day of the first month which begins more than 4 weeks after the date of the enactment of [the Act]; or (B) the date on which the Secretary of Health and Human Services lists any vaccines against influenza for purposes of compensation for any vaccine-related injury or death through the Vaccine Injury Compensation Trust Fund.'' It further provides that if the vaccines were sold before or on the effective date of the excise tax, but delivered after this date, the delivery date of such vaccines shall be considered the sale date.

Under this authorizing statutory language, the Secretary may choose to use December 1, 2004, or a later date as effective date of coverage, imposing the excise tax for trivalent influenza vaccines on this effective date. On November 10, the Advisory Commission on Childhood Vaccines voted to recommend July 1, 2005, as the effective date for the imposition of excise tax on trivalent influenza vaccines. Imposition of a new excise tax in the middle of this 2004–2005 influenza season may cause confusion and possibly impede the prompt sale and/or distribution or redistribution of influenza vaccines. To