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

avoid any confusion and possible effects on the prompt sale and/or distribution of such vaccine, the Secretary has determined that the effective date for the enactment of the excise tax for trivalent influenza vaccines should be July 1, 2005. Thus, trivalent influenza vaccines are included as covered vaccines under Category XIV of the Table as of July 1, 2005. Petitioners may file petitions related to trivalent influenza vaccines as of July 1, 2005.

Petitions filed concerning vaccine-related injuries or deaths associated with trivalent influenza vaccines must be filed within the applicable statute of limitations. The filing limitations applicable to petitions filed with the VICP are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)). In addition, section 2116(b) of the PHS Act lays out specific exceptions to these statutes of limitations that apply when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this provision, persons who may be eligible to file petitions based on the addition of a new vaccine under Category XIV of the Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)). Thus, persons whose petitions may not be timely under the limitations periods described in section 2116(a) of the PHS Act, may still file petitions concerning vaccine-related injuries or deaths associated with trivalent influenza vaccines until July 1, 2007, as long as the vaccine-related injury or death occurred on or after July 1, 1997 (8 years prior to the effective date of the addition that included trivalent influenza vaccines as covered vaccines).

The Secretary plans to amend the Table through the rulemaking process by including trivalent influenza vaccines as a separate category of vaccines in the Table. July 1, 2005, will remain the applicable effective date when the Secretary makes a corresponding amendment to add trivalent influenza vaccines as a separate category on the Table through rulemaking.

Dated: April 5, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–7264 Filed 4–11–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4978–N–03]

Notice of Proposed Information Collection for Public Comment; Indian Housing Operating Cost Study

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* June 13, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Aneita Waites, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4114, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Aneita Waites, (202) 708–0713, extension 4114, for copies of proposed forms and/or other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Indian Housing Operating Cost Study, 1937 Act Housing Operating Costs Survey.

OMB Control Number: 2577–XXXX [to be assigned].

Description of the need for the information and proposed use: The Indian Housing Block Grant (IHBG) formula uses Allowable Expense Level (AEL) data in determining the operating subsidy portion of the IHBG grant for Tribes that continue to operate housing units developed under 1937 Act programs. During recent Formula Negotiated Rulemaking Committee sessions several Committee members indicated that AEL did not adequately recognize the real cost of operating housing in Indian Country and that the AEL values needed to be replaced with a more current, accurate measure of the costs to operate housing in tribal areas. HUD committed to working with the Tribes to address this concern. There is no database with information about current operating costs of 1937 Act housing programs in Indian Country. The information gathered in this form will be used to establish a current, accurate cost database, and will support continued discussions on the role of AEL in the IHBG formula.

Agency form number, if applicable: Not applicable.

Members of affected public: Tribal Governments.

Estimation of the total number of hours needed to prepare the information collection including number of respondents: 269 tribally designated housing entities (TDHEs) manage the 1937 Act housing for Tribes. Estimated response time is 2 hours. Estimated total responses based on 75% return rate is 202. Estimated total reporting burden is 404 hours.

Status of the proposed information collection: New collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: April 1, 2005.

Michael Liu,

Assistant Secretary for Public and Indian Housing.

[FR Doc. E5–1656 Filed 4–11–05; 8:45 am]

BILLING CODE 4210–27–P