SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Lot Release Protocols'' dated July 2006. This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research'' dated May 1998 (63 FR 29742, June 1, 1998). The guidance announced in this notice was revised based on public comments submitted to the Division of Dockets Management on the draft guidance. The guidance is intended to provide manufacturers of biological products regulated by CBER with recommendations for submitting to CBER Product Release Branch lot release protocols in electronic format.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 610.2(a) have been approved under OMB control number 0910–0206.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. 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 the guidance 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11040 Filed 7–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), 42 U.S.C. 300aa–1 *et seq.*, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: The agency must receive nominations on or before August 14, 2006.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl A. Lee, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, HSB, HRSA at (301) 443–2124 or e-mail: *clee@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, and the Federal Advisory Committee Act of October 6, 1972, 5 U.S.C. App., HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying Federal, State, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows: Three health professionals, who are not employees of the United States Government and have expertise in the healthcare of children; and the epidemiology, etiology, and prevention of childhood diseases; and the adverse reactions associated with vaccines, at least two of whom shall be pediatricians; three members from the general public, at least two of whom shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A health professional who has expertise in the healthcare of children and the epidemiology, etiology, and prevention of childhood diseases; (2) an attorney whose specialty includes representation of a vaccine manufacturer; and (3) a member of the general public. Nominees will be invited to serve a 3-year term beginning January 1, 2007, and ending December 31, 2009.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to

serve as a member of the ACCV and appears to have no conflicts of interest that would preclude the ACCV membership. Potential candidates will be asked to provide detailed information concerning consultancies, research grants, or contracts to permit evaluation of possible sources of conflicts of interest. A curriculum vitae or resume should be submitted with the nomination.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or disabled candidates.

Dated: July 7, 2006.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E6–11039 Filed 7–12–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 60-day proposed information collection: Indian Health Service Contract Health Service Report.

SUMMARY: The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the IHS is providing a 60-day advance opportunity for public comment on a proposed new collection of information to be submitted to the Office of Management and Budget for review.

Proposed Collection:

Title: 0917–0002, '' Indian Health Service Contract Health Service Report''.

Type of Information Collection Request: Extension, without revision, of currently approved information collection 0917–0002, ''Indian Health Service Contract Health Service Report''.

Form Number: IHS 843–1A.

Need and Use of Information Collection: The purpose for the collection is to authorize contract health care providers to provide health care services to eligible IHS patients. The IHS form 843–1A ''Order for Health Services'' was developed specifically for this collection of information. Other than revising the title ''Purchase-Delivery Order for Health Services'' to read ''Order for Health Services'', acquisition terms on the front of the form, the contract clauses contained on the back of copy 3 of the form, the form has not been revised and there is no change in the substance or in the use of the form. A copy of the form is at Attachment 2.

The majority of the information contained in this form is completed by IHS staff from existing IHS automated patient and vendor data files. Contract health care providers complete and sign the streamlined form and submit it, along with a completed standard Centers for Medicare & Medicaid Services (CMS) health claim form (CMS 1450 (UB 92) and CMS 1500), to the IHS for verification and payment. The CMS forms are used and accepted nation-wide by the health care industry and IHS is an approved user.

The information collection is needed to administer and manage the contract health care services provided to eligible American Indian and Alaska Native patients. The form is used to: Authorize contract health care services for eligible patients; certify that the health care services requested and authorized have been performed by the contract provider(s); process payments for health care services performed by such providers; obtain program data; and, serve as a legal document for health and medical care authorized by the IHS and rendered by health care providers under contract with the IHS.

The information collected is also used for: Planning for further care of the patient; for keeping an accurate record of the patient's health status and health services received and recommended; for planning future health care programs; for communicating among members of the health care team; for evaluating the health care rendered; for research and continuing education; and, for the provision of program health statistics.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

Burden Hours: The table below provides the estimated burden hours for this information collection:

Data collection instrument	Estimated number of respondents	Responses per respondent	Annual number of responses	Burden per response *	Total annual burden hours
IHS–843–1A	7,399	42	272,506	0.05 (3 mins)	13,625.3
IDS**	13,717	1	13,717	0.05 (3 mins)	685.8
Total	21,116				14,311.1

* For ease of understanding, burden hours are provided in actual minutes.
** Inpatient Discharge Summary (IDS).

There are no capital costs, operating costs and/or maintenance costs to respondents.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests for Further Information: For the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Mrs. Christina Rouleau,