Bank. It included information on the types of clinical trials for which submissions will be required under section 113 of the Modernization Act, as well as the types of information to be submitted. The draft guidance stated that an implementation plan, addressing procedural issues, would be available later. The draft guidance stated that the implementation plan would include: (1) Information on how to submit protocols to the Clinical Trials Data Bank, (2) information about providing certification to the Secretary that disclosure of information for a particular protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation, (3) discussion about issues related to the voluntary submission of information not required by section 113 of the Modernization Act (e.g., study results, trials for non-serious or non-life-threatening diseases), and (4) a timeframe for submitting the information.

In developing a plan for making publicly available information from the Clinical Trials Data Bank, FDA and NIH considered comments submitted to Docket Nos. 98D–0293 and 00D–1033, ''Section 113 NIH Data Bank—Clinical Trials for Serious Diseases.'' A phased approach was used for developing guidance. A first draft guidance (the March 29, 2000, draft guidance) addressed general information on the scope of the data bank. The draft guidance being made available by this notice discusses procedures that were not included in the first guidance. This draft guidance was developed based on the initial data bank experience using NIH-sponsored trials. A final guidance will be developed that combines the informational and procedural draft guidances and considers comments received on both of the draft guidances.

Section 113(a) of the Modernization Act requires that sponsors of INDs submit to the Clinical Trials Data Bank a description of the purpose of each experimental drug, eligibility criteria for participation in the trial, the location of clinical trial sites, and a point of contact for those wanting to enroll in the trial. The statute requires that the information be provided in a form that can be readily understood by members of the public. This draft guidance provides information on how IND sponsors can fulfill the requirements of section 113(a) of the Modernization Act by submitting information in the following four areas: (1) Descriptive information, (2) recruitment information, (3) location and contact information, and (4) administrative information. FDA and NIH developed these data elements based on the legislative requirements and comments submitted to Docket No. 98D–0293. Information will be submitted to the Clinical Trials Data Bank through a Web-based Protocol Registration System (PRS). For a preview of the PRS system see http://prsinfo.clinicaltrials.gov/.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on submitting information on clinical trials for serious or life-threatening diseases to a Clinical Trials Data Bank developed by the NLM. 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. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, 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 draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA published notice of a proposed collection of information, along with the first draft guidance, in the **Federal Register** on March 29, 2000. On November 9, 2000 (65 FR 67385), FDA published a notice that the proposed collection of information was submitted to OMB for review. The report considered comments received on the proposed collection of information. On March 23, 2001 (66 FR 16251), as corrected on April 17, 2001 (66 FR 19788), FDA announced OMB's approval of the agency's information collection activities for the program (OMB Control No. 0910–0459).

IV. Electronic Access

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

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17050 Filed 7–6–01; 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 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: The National Health Service Corps (NHSC) Loan Repayment Program (OMB No. 0915–0127)—Extension

The NHSC LRP was established to assure an adequate supply of trained primary care health professionals to the neediest communities in the Health Professional Shortage Areas (HPSAs) of the United States. Under this program, the Department of Health and Human Services agrees to repay the educational loans of the primary care health professionals. In return, the health professionals agree to serve for a specified period of time in a federally-designated HPSA approved by the Secretary for LRP participants.

This request for extension of OMB approval will include the NHSC LRP Application, Loan Verification Form, Site Information Form and Request for Method of Advanced Loan Repayment Form.

The estimate of burden is as follows:

Type of respondents	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Applicants	800	1	800	1.5	1200
Lenders	45	1	45	.25	11
Total	845		845		1211

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 2, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–17053 Filed 7–6–01; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration.

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), as enacted by Public Law (P.L.) 99–660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl A. Lee, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, at (301) 443–2124.

DATES: Nominations are to be submitted by August 8, 2001.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, HRSA, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, via the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463) and section 2119 of the Act, 42 U.S.C. 300aa–19, as added by Pub. L. 99–660 and amended, 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, National Vaccine Program Office 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 health care of children, the epidemiology, etiology and prevention of childhood diseases, and the adverse reactions associated with vaccines, at least two shall be pediatricians; three members from the general public, at least two are legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and three attorneys, at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and 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 pediatrician with special experience in childhood diseases; (2) an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death; and (3) a member from the general public who is a legal representative (parent or legal guardian) of a child who has suffered a vaccine-related injury or death. Nominees will be invited to serve 3-year terms beginning January 1, 2002, and ending December 31, 2004.

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 conflict 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