collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. Emergency approval is needed because this collection's expiration inadvertently lapsed.

CMS is requesting OMB review and approval of this collection by August 8, 2003, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by July 31, 2003. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Request for Review of Part B Medicare Claim and Supporting Regulations in 42 CFR Section 405.807; *Form No.:* CMS–1964 (OMB# 0938–0033); *Use:* This form is the preferred manner to enable appellants to request a Part B review by a carrier.; *Frequency:* On occasion; *Affected Public:* Individuals or Households and Not-for-profit institutions; *Number of Respondents:* 6,860,000; *Total Annual Responses:* 6,860,000; *Total Annual Hours:* 1,715,000.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by July 31, 2003: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–0262, Attn: Melissa Musotto CMS 10091; and, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Brenda Aguilar, CMS Desk Officer.

Dated: July 10, 2003.

Melissa Musotto,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–18530 Filed 7–21–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0302]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certain Biologics Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements related to certain biologics labeling requirements.

DATES: Submit written or electronic comments on the collection of information by September 22, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under 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 is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Certain Biologics Labeling

Under the authority of section 351 of the Public Health Services Act (PHS Act) (42 U.S.C. 262), the biologics regulations require a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce part 601.2 (21 CFR part 601.2). In addition, any changes to labeling are required to be submitted to FDA for review and approval (§ 601.12). For

biological products, excluding blood and blood components for transfusion, the container and package labeling requirements subject to the PRA are provided in part 610.60 (21 CFR part 610.60) §§ 610.61, and § 610.62. The collections of information under §§ 601.2, 601.12, 610.60, 610.61, and 610.62 are approved under OMB control number 0910–0338 (expires August 31, 2005). In addition to the labeling requirements prescribed in §§ 610.60 through 610.62 or other labeling regulations (e.g., § 809.10), there are additional container and/or package labeling requirements for certain licensed biological products subject to the PRA: §§ 640.70 and 640.74 (21 CFR 640.70 and 640.74) (Source Plasma), § 640.84 (Albumin), § 640.94 (Plasma Protein Fraction), § 660.2 (Antibody to Hepatitis B Surface Antigen), § 660.28 (Blood Grouping Reagent), § 660.35 (Reagent Red Blood Cells), § 660.45 (Hepatitis B Surface Antigen), and § 660.55 (Anti-Human Globulin).

An example of an additional labeling requirement for each of the specific regulations is as follows:

- Section 640.70(a), the total volume or weight of plasma.
- Section 640.74(b)(3) and (4), the name of the manufacturer of the final blood derivative product for whom it was prepared.
- Sections 640.84(a) and (c), and 640.94(a), the osmotic equivalent.
- Section 660.2(c), name of the recommended test method(s).
- Section 660.28(a) and (b), the name of the antibody or antibodies present.
- Section 660.35(a), (c) through (g), and (i) through (m), information regarding washing of cells, percentage of red blood cells in suspension.
- Section 660.45, name of the recommended test method(s).
- Section 660.55(a) and (b), the name of the antibody or antibodies present.

Form FDA 2567 ''Transmittal of Labels and Circulars'' is used by manufacturers of licensed biological products to submit with labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. Labeling information is submitted to FDA for review in an application, supplement or, when appropriate, an annual report. Form FDA 2567 is approved under OMB control number 0910–0338.

Based on information obtained from CBER's database system, there is an estimated 350 manufacturers of licensed biological products. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses are based on the estimated number of submissions for a particular product (e.g., license applications and labeling supplements) received annually by FDA. No applications have been received for most of the listed products in the last couple of years, but FDA is using the estimate of one application in the event one is submitted in the future. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years.

The hours per response is based on past FDA's experience with the various submissions to FDA and includes the time estimated to prepare the various submissions for FDA review and collate the documentation. The burden associated with the additional labeling requirements for submission in a license application is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.62 or other labeling requirements. FDA estimates that it takes between 10 to 40 hours (average 25 hours) to complete a labeling supplement or annual report for submission to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Type of Submission	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
640.70(a) and 640.74(b)(3) and (4)	application	5	1	5	2	10
	supplement	20	1.5	30	25	750
640.84(a) and (c)	application	1	1	1	1	1
	supplement	3	1.25	4	25	100
640.94(a)	application	1	1	1	1	1
	supplement	1	1	1	25	25
660.2(c)	application	1	1	1	3	3
	supplement	1	1	1	25	25
660.28(a) and (b)	application	1	1	1	6	6
	supplement	1	2	2	25	50
660.35(a)(c) through (a)(g) and 660.35 (a)(i) through (a)(m)	application	1	1	1	6	6
	supplement	1	1	1	25	25
660.45	application	1	1	1	3	3
	supplement	1	1	1	25	25
660.55(a) and (b)	application	1	1	1	6	6
	supplement	1	1	1	25	25
Total						1,061

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–18503 Filed 7–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission of 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), as enacted by Public Law (Pub. 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).

DATES: The agency must receive nominations on or before August 21, 2003.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Office of Special Programs, HRSA, Parklawn Building, Room 16C–17, 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, at (301) 443–2124 or e-mail:*clee@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, 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 Public Law 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 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 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 shall be 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 a vaccine manufacturer; and (3) a member from the general public. Nominees will be invited to serve a 3-year term beginning January 1, 2004, and ending December 31, 2006.

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 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 physically disabled candidates.

Dated: July 10, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–18567 Filed 7–21–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA–03–039]

Fiscal Year 2003 Competitive Application Cycle for the Healthy Communities Access Program (HCAP); CFDA Number 93.252

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds for new awards.

Legislative Authority: The ''Health Care Safety Net Amendments of 2002'' (Pub. L. 107–251) amended Part D of Title III of the Public Health Service (PHS) Act by inserting a new Subpart V, Section 340, creating the Healthy Communities Access Program (HCAP). Section 340 of the PHS Act (42 U.S.C. 256) authorizes the award of competitive grants to eligible entities to assist in the development of integrated health care delivery systems to serve communities of individuals who are uninsured and/or underinsured.

Purpose: To provide assistance to communities and consortia of health care providers and others they represent to develop or continue activities to strengthen integrated community health care delivery systems that coordinate health care services for individuals who are uninsured or underinsured, and to develop or strengthen activities related to providing coordinated care for individuals with chronic conditions who are uninsured or underinsured.

Eligibility: Tribal, faith-based and community-based organizations are encouraged to apply. For an entity to be eligible to receive a new HCAP award, the following requirements must be met:

1. The applicant entity must represent a consortium whose principal purpose