

provision of the BPCA, FDA has posted on the Internet (<http://www.fda.gov/cder/pediatric/index.htm>) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Ciloxan (ciprofloxacin ophthalmic), Brevibloc (esmolol), Flovent (fluticasone), Fludara (fludarabine), Fosamax (alendronate), Lotensin (benazepril), Malarone (atovaquone and proguanil), Xenical (orlistat), and Ocuflax (ofloxacin ophthalmic). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: February 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA)

publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Presidential Initiative Application Forms for Funding Opportunities—In Use Without Approval

The Consolidated Health Center Program is administered by the Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC). Grant funding opportunities are provided for Health Centers under the Presidential Initiative to expand health centers. These funding opportunities use the following applications: New Access Point Funding (NAP), Service Area Competition (SAC), the Expanded Medical Capacity (EMC) for Consolidated Health Centers and the Service Expansion (SE). These application forms are used by new and current Health Centers to apply for funding.

The five-year President's Initiative to Expand Health Centers will significantly impact 1,200 of the Nation's neediest communities by creating new health center sites. Additional emphasis will be given to improving and strengthening existing sites and expanding existing centers.

BPHC will assist in achieving the Initiative through the various funding opportunities under this Initiative. This year's funding increase supported the development of an additional 100 new access points and 88 significantly expanded access points. New access points will be established by Health Centers targeting the neediest communities using successful Center models. Expanded capacity will be targeted to communities where an existing Health Center's ability to provide care falls short of meeting the full need for services to uninsured and underserved populations. Funding will be provided to Health Centers to support the staff needed to serve a substantial increase in users.

Estimates of annualized reporting burden are as follows:

Type of application form	Number of respondents	Hours per response	Total burden hours
NAP	500	60	30,000
SAC	250	50	12,500
EMC	225	25	5,625
SE	450	25	11,250
Total	1,425	59,375

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 12, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-3647 Filed 2-18-04; 8:45 am]

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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) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) will publish 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, 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 Smallpox Vaccine Injury Compensation Program (OMB No. 0915-0282)—Extension

The Smallpox Emergency Personnel Protection Act (SEPPA) authorized the Secretary of Health and Human Services to establish The Smallpox Vaccine Injury Compensation Program, which is designed to provide benefits and/or compensation to certain persons harmed as a direct result of receiving smallpox covered countermeasures, including the

smallpox vaccine, or as a direct result of contracting vaccinia through certain accidental exposures.

The benefits available under the Program include compensation for medical care, lost employment income, and survivor death benefits. To be considered for Program benefits, requesters (*i.e.*, smallpox vaccine recipients, vaccinia contacts, survivors, or the representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), or persons filing on their behalf as their representatives, must file a Request Form and the

documentation required under this regulation to show that they are eligible.

Requesters must submit appropriate documentation to allow the Secretary to determine if the requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is filing as a smallpox vaccine recipient, a vaccinia contact, a survivor, or a representative of an estate. All requesters must submit medical records sufficient to demonstrate that a covered injury was sustained by a smallpox vaccine recipient or a vaccinia contact.

The burden estimate is as follows:

Form	Number of respondents	Responses per respondent	Hourly response	Total burden hours
Request Form	1,250	1	5	6,250
Certification	1,250	1	1	1,250
Total	2,500	7,500

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

Dated: February 12, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-3648 Filed 2-18-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; Revision of OMB No. 0925-0001/exp. 05/31/04, "Research and Research Training Grant Applications and Related Forms"

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Research and Research Training Grant Applications and Related Forms. *Type of Information Collection Request:* Revision, OMB 0925-001, Expiration

Date 5/31/04. Form Numbers: PHS 398, 2590, 2271, 3734 and HHS 568. *Need and Use of Information Collection:* The application is used by applicants to request Federal assistance for research and research-related training. The other related forms are used for trainee appointment, final invention reporting, and to relinquish rights to a research grant. *Frequency of response:* Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed. *Affected Public:* Individuals or Households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* Adult scientific professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:* 122,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 8.5; and *Estimated Total Annual Burden Hours Requested:* 1,032,439. The estimated annualized cost to respondents is \$49,245,180.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number (301) 435-0941, or E-mail your request, including your address to: [curriem@od.nih.gov]

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: February 11, 2004.

Joe Ellis,

Acting Director, OPERA, OER, National Institutes of Health.

[FR Doc. 04-3525 Filed 2-18-04; 8:45 am]

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