

on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### V. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 11, 2007.  
**Jeffrey Shuren**,  
*Assistant Commissioner for Policy.*  
 [FR Doc. E7-18221 Filed 9-14-07; 8:45 am]  
**BILLING CODE 4160-01-S**

### 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 (OMB), 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: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915-0184): Extension**

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, to ensure that all qualified entities are accepted for membership in the OPTN, and to ensure patient safety.

#### ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN

Section and activity	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
121.3(b)(2)—OPTN membership and application requirements for OPOs, hospitals, and histocompatibility laboratories .....	40	3	120	15	1,800
121.3(b)(4)—Appeal for OPTN membership .....	2	1	2	3	6
121.6(c) (Reporting)—Submitting criteria for organ acceptance .....	900	1	900	0.5	450
121.6(c) (Disclosure)—Sending criteria to OPOs .....	900	1	900	0.5	450
121.7(b)(4)—Reasons for Refusal .....	900	38	34,200	0.5	17,100
121.7(e) —Transplant to prevent organ wastage .....	260	1.5	390	0.5	195
121.9(b)—Designated Transplant Program Requirements .....	10	1	10	5.0	50
121.9(d)—Appeal for designation .....	2	1	2	6	12
<b>Total .....</b>	<b>954</b>	<b>.....</b>	<b>36,524</b>	<b>.....</b>	<b>20,063</b>

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: September 10, 2007.  
**Alexandra Hutteringer**,  
*Acting Director, Division of Policy Review and Coordination.*  
 [FR Doc. E7-18220 Filed 9-14-07; 8:45 am]  
**BILLING CODE 4165-15-P**

### 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 (OMB), 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 OMB for review under the Paperwork Reduction Act of 1995:

##### **Proposed Project: The Nurse Faculty Loan Program (NFLP): Annual Operating Report (AOR) Form—NEW**

The Annual Operating Report (AOR) provides information on the Nurse Faculty Loan Program (NFLP) funded loan activities. Under Title VIII of the Public Health Service Act, as amended by Public Law 107-205, Section 846A, the Secretary of Health and Human Services (HHS) enters into an agreement with a school of nursing to establish and operate the NFLP fund. HHS makes an

award to the school in the form of a Federal Capital Contribution (FCC). The award is used to establish a distinct account for the NFLP loan fund at the school or is deposited into an existing NFLP fund. The school of nursing makes loans from the NFLP fund to eligible students enrolled full-time in a master's or doctoral nursing education program that will prepare them to become qualified nursing faculty. Following graduation from the NFLP lending school, loan recipients may receive up to 85 percent NFLP loan cancellation over a consecutive four-year period in exchange for service as full-time faculty at a school of nursing. The NFLP lending school collects any

portion of the loan that is not cancelled. The lending school deposits monies from loan collection and repayment into the NFLP loan fund to make additional NFLP loans. The school of nursing must keep records of all NFLP loan fund transactions.

The NFLP Annual Operating Report is used to collect information relating to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). Participating schools will complete and submit an electronic copy of the AOR annually to provide the Federal Government with current and cumulative information on:

- (1) The number and amount of loans

made, (2) the number of NFLP recipients and graduates, (3) the number and amount of loans collected, (4) the number and amount of loans in repayment, (5) the number of NFLP graduates employed as nurse faculty, and (6) NFLP loan fund receipts, disbursements and other related costs. The NFLP loan fund balance is used with other criteria to determine the annual award to the school.

Once the AOR is completed by the participating school, the AOR will be submitted electronically through the HRSA Electronic Handbook.

The estimate of burden for this form is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Nurse Faculty Loan Program Annual Operating Report (AOR) .....	150	1	150	8	1200
Total Burden .....	150	1	150	8	1200

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: September 10, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Suppression of Allergic Asthma by *Ascaris* Antigens

**Description of Technology:** Available for licensing and commercial development are compositions and methods for suppressing allergic reactions, as well as Th-1 and Th-2 associated immunological diseases, by administering any of the two identified *Ascaris* polypeptide antigens, or active fragments or variants thereof, to the affected subject.

Allergic asthma is characterized by antigen-specific IgE production, reversible airway hyper-reactivity and eosinophilic infiltration of the airways. There is a dramatic increase in the prevalence of allergic disorders in emerging and industrialized countries and studies suggest that the hygienic environment in those countries may not provide allergy-protective mechanisms associated with some forms of infection. Recent studies have found that helminth infection may suppress the development of allergic disease. Helminth infections currently affect over 2 billion people

worldwide, causing significant morbidity. The most successful geohelminths are members of the *Ascaris* species, including *A. lumbricoides* and *A. suum*, which are known to infect 1.5 billion people. The inventors studied the modulation of allergic disease mediated by a chronic *A. suum* infection in their murine model of ragweed-induced allergic conjunctivitis and allergic asthma, and demonstrated that the infection prevents allergic inflammation in sites distal from larval migration. This protection was due, in part, to the induction of immunoregulatory cytokines such as IL-10. In further studies, they demonstrated that a cocktail of antigens from the pseudocoelomic fluid (PCF) of *A. suum*, administered during ragweed sensitization, significantly reduced the eosinophil migration into the conjunctiva, pulmonary eosinophilic inflammation, and total lung pathology induced by the ragweed. PCF exposure also reduced the secretion of the pro-allergic cytokines IL-5 and IL-13 in the broncho-alveolar lavage fluid after ragweed exposure. All findings suggest PCF is capable of suppressing the allergic response to a traditional allergen and at multiple tissue sites.

In further studies, the inventors determined that the protection conferred by PCF to allergic inflammation was through a specific first antigenic protein isolated from PCF, results that were confirmed by using the recombinant form of the first antigen.