and grantees, as a condition for a funding award, to submit review protocols or criteria that FDA can use in performing premarket reviews of breakthrough products used in the prevention, diagnosis and treatment of oral, dental and cranio-facial diseases and conditions. [S]

• Investigation into methods by which NIDR and FDA can jointly and individually promote the availability and use of FDA's adverse incident reporting systems (e.g., MedWatch) among oral health professionals and other health and dental product user groups. [S]

• Enlistment of NIDR technical, statistical and clinical experts to assist FDA in the design and content development of guidance documents that FDA product reviewers can use to assess product safety and effectiveness. [L]

D. Fellowship Sponsorship

• Investigation into the merits and legal aspects of establishing non-Federal fellowships in which interested parties from the private sector would subsidize individuals with an interest in FDA regulatory processes for one-year residency periods. Under such an arrangement, NIDR could serve as fiduciary in order to prevent appearances of conflict-of-interest. Fellowship assignments would entail generalized exposure to and experience with FDA regulatory procedures so as to also avoid access to protected, product-specific information that could be used for competitive advantage. Fellows would also be subjected to the controls, rights, privileges and restrictions to which all other FDA-recruited special government employees are subjected. [L]

E. Policy Development

• Continuation of current interchanges and expert consultations on selected policy issues that engender wide-scale interest among consumers and/or oral health professionals, involve products or therapies that pose a known or potential health risk to the general public, relate to research and regulatory processes affecting the pace of technology transfer, etc. This activity should extend to other matters of major import such as the Surgeon General's report on oral health which NIDR has been charged to produce and to which FDA can substantively contribute. [I]

F. Research

• Continuation of ongoing research collaborations, such as those between CBER and NIDR's Division of Intramural Research.

• Coordination of NIDR's biological and clinical resources and the CDRH's engineering and life sciences expertise to address a number of diverse issues relating to cleaning, infection and sensitivity reactions to new biomaterials. [S]

• Establishment of one or more patient registries for purposes of monitoring adverse incidents linked to particular dental products in addition to product-specific performance trends. Such an activity could be jointly undertaken by FDA and NIDR, as well as in conjunction with involvement by other organizations such as USP and various dental professional and product user organizations. [L]

• Initiation of collaborative research aimed at developing fundamental data and methods needed to assess long-term performance of dental devices and systems. Such research could include the joint development of physical, animal and computer-based models to adequately evaluate long-term clinical performance of marketed and evolving dental devices (e.g., osseous integration of dental implants, fatigue performance of ceramic porcelains, etc.). [L]

G. Advisory Committee & Study Section Review/Appointments

• Provision of ad hoc or liaison status to FDA officials on the NIDR National Advisory Dental Research Council (including access to closed sessions of the Council on a case-by-case, need-to-know basis), in addition to DRG and other study sections/review groups for the purpose of assisting NIDR in its review of extramural research submissions. [S]

• Expansion of current NIDR participation as consultants and/or Federal liaisons on dental-related advisory committees and panels managed by FDA (including access to closed sessions on a case-by-case, need-to-know basis) for the purpose of augmenting the scientific and clinical expertise that is brought to bear on product applications and proposed policies on which outside advice is sought by the agency. [S]

• Formal solicitation of advice by each party from the other on candidate nominations for appointment to NIDR and FDA review and advisory bodies. [S]

[FR Doc. 98–14462 Filed 6–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collections; Comment Request: National Institutes of Health Construction Grants

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 the Director (OD), 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:* National Institutes of Health Construction Grants (42 CFR Part 52b). *Type of Information Collection Request:* Extension of OMB No. 0925–0424, expiration date 09/30/98. *Need and Use of Information Collection:* This is a request for OMB approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR Part 52b. The purpose of the regulations is to govern the awarding and administration of grants awarded by NIH and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the building (or applicable part of the building) suitable for the purpose for which it was constructed. In terms of reporting requirements:

Section 52b.9(b) of the proposed regulations requires the transferor of a facility which is sold or transferred, or the owner of a facility, the use of which has changed, to provide written notice of the sale, transfer or change within 30 days. Section 52b.10(f) requires a grantee to submit an approved copy of the construction schedule prior to the start of construction. Section 52b.10(g) requires a grantee to provide daily construction logs and monthly status reports upon request at the job site. Section 52b.11(b) requires applicants for a project involving the acquisition of existing facilities to provide the estimated costs of the project, cost of the acquisition of existing facilities, and cost of remodeling, renovating, or altering facilities to serve the purposes for which they are acquired.

In terms of recordkeeping requirements: Section 52b.10(g) requires grantees to maintain daily construction logs and monthly status reports at the job site. *Frequency of Response:* On occasion. *Affected Public:* Non-profit organizations and Federal agencies. *Type of Respondents:* Grantees. The estimated respondent burden is as follows:

	Estimated annual reporting and recordkeeping burden			
	Annual number of respondents	Annual frequency	Average burden per	Annual burden hours
Reporting:				
§ 52b.9(b)	1	1	.50	.50

	Estimated annual reporting and recordkeeping burden			
	Annual number of respondents	Annual frequency	Average burden per	Annual burden hours
§ 52b.10(f)	15	1	1	15
§ 52b.10(g)	30	12	1	360
§ 52b.11(b)	100	1	1	100
Recordkeeping:				
§ 52b.10(g)	30	260	1	7,800
Total	176			8,275.50

The annualized cost to the public, based on an average of 30 active grants in the construction phase, is estimated at: $273,000.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information and recordkeeping are necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information and recordkeeping, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected and the recordkeeping information to be maintained; and (4) 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 and recordkeeping techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

To request more information contact Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852, or call 301–496–4607 (this is not a toll-free number), or E-mail your request to <moorej@OD.NIH.gov.>

Comments Due Date: Comments regarding this information collection and recordkeeping are best assured to having their full effect if received on or before August 3, 1998.

Dated: May 27, 1998.

Jerry Moore,

Regulations Officer, National Institutes of Health.

[FR Doc. 98–14498 Filed 6–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: DNA Vaccines for Chlamydia Trachomatis

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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 and issued patent listed below may be obtained by contacting Robert Benson, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7056 ext. 267; fax: (301) 402–0220; e-mail: rb20m@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Nucleotide, Deduced Amino Acid Sequence, Isolation and Purification of Heat-Shock Chlamydial Proteins

RB Morrison, HD Caldwell (NIAID)

Serial No. 07/531,317 Filed 31 May 90 (U.S. Patent 5,071,962 Issued 10 Dec. 91); Serial No. 07/841,323 Filed 25 Feb. 92 (Divisional of 07/531,317); Serial No. 09/071,506 Filed 01 May 98 (Divisional of 07/841,323)

This invention concerns the discovery of a novel gene that encodes the HSP60 protein from *Chlamydia trachomatis*, referred to as HypB in the application. This immunodominant protein is a major target for *Chlamydia trachomatis* vaccine development and diagnostics. This gene and protein, or fragments thereof, are useful in the development of both recombinant protein and DNA based vaccines. The recombinant protein or DNA sequence also have potential for the development of diagnostic tests for *C. trachomatis*. The three patent properties claim different aspects of the invention. The issued patent claims monoclonal antibodies reactive against *C. trachomatis* HSP60 protein. Serial No. 07/841,323 claims the HSP60 protein and its use as a vaccine. Serial No. 09/071,506 claims DNA sequences, and protein fragments thereof, encoding HSP60. This DNA sequence would be useful in a DNA vaccine, alone or with the MOMP DNA sequences claimed in Serial No. 07/853,359. No foreign patent rights exist.

Nucleotide and Amino Acid Sequences of the Four Variable Domains of the Major Outer Membrane Proteins of Chlamydia Trachomatis

H Caldwell et al. (NIAID)

Serial No. 07/853,359 Filed 16 Mar. 92 (With Priority to 17 Mar. 89)

Chlamydia trachomatis is the leading sexually transmitted infectious agent in the United States, causing about 10 million new cases per year. It is a major cause of involuntary infertility in women. This invention claims the DNA sequences, and their encoded amino acid sequences, of the four variable domains from the major outer membrane protein (MOMP) of *Chlamydia trachomatis*, from the serovars Ba, D, E, F, G, H, I, J, K, and L3. Serovars D, E, F, G, H, I, J, and K are the most common serovars associated with *Chlamydia trachomatis* caused sexually transmitted diseases. The claimed variable domains of MOMP contain the major antigen targets of protective immunity including neutralizing antibodies capable of preventing chlamydial infection. Thus, these sequences are useful for the development of recombinant protein, peptide, and DNA based vaccines