

period of time. Written comments and suggestions regarding operation of the electronic docket are acceptable at any time. Cessation of the public docket is effective immediately.

ADDRESSES: Submit written comments on the management of the electronic docket to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597.

SUPPLEMENTARY INFORMATION:

Throughout its existence, the Center for Devices and Radiological Health (CDRH) has employed a number of outlets to communicate with regulated industry, the medical community, and interested consumers about its policies and operations. Although these modes of communication were generally regarded as effective, many persons expressed the desire for even broader access to CDRH-generated information to better assist them in complying with FDA regulatory requirements. In response, CDRH created two dockets to serve as readily accessible repositories of current and important materials. FDA announced the establishment of both dockets in the **Federal Register** of July 27, 1993 (58 FR 40150), and stated there would be a 1-year trial period for both information retrieval systems.

One docket, from which documents in "hard copy" form can be acquired, has been located at the Dockets Management Branch (address above). Interested persons were required to physically visit this facility in order to access the information.

CDRH also established an electronic docket as a means to further increase industry access to policy documents. This menu-driven system allows interested persons to access, read, print, and download documents using personal computers at their places of business.

Throughout the pilot year, CDRH has monitored the number of inquiries received through each of the two dockets. Approximately 100 document requests were made through the public ("hard copy") docket. In contrast, more than 17,000 inquiries were received through the electronic docket, and the number of system accesses continues to increase. During the period August through September 1994, slightly more than 5,800 requests were made. In addition to these utilization statistics, CDRH has taken note of articles,

editorials in trade publications, and correspondence that have commented favorably about the usefulness of the electronic docket in particular.

In view of the positive feedback on the electronic docket, as reflected by the comparatively large volume of inquiries, the agency believes there is sufficient justification for maintaining this public service. Persons interested in availing themselves of this information access system must have a video terminal or personal computer with communications software (VT emulation) and a modem that can operate at a baud rate of 1200, 2400, 4800, or 9600. For those persons who wish to transfer files from the electronic docket, the KERMIT file transfer protocol must be used. The telephone number to access the system is 1-800-252-1366 or 301-594-2741.

From the experience gained in operating the electronic docket, CDRH is contemplating a number of refinements to improve its information delivery capability, as well as the scope of material available for public access. These will include, for example, announcements of upcoming meetings of the agency's various medical device advisory panels. As other enhancements to the system are introduced, CDRH will inform potential users through CDRH newsletters, trade publications, public speeches, and other communication vehicles.

Effective immediately, FDA is terminating the public docket pilot program. Because of the marginal utilization of the public docket, CDRH believes that the administrative costs associated with its operation are no longer justified.

The actions announced in this notice do not affect the status of two other information access systems referred to in the **Federal Register** notice of July 7, 1993: (1) The CDRH "Flash FAX" system, from which virtually all documents formerly offered in the public docket are presently or shortly will be available; and (2) the premarket notification (510(k)) submission status reporting system.

To receive information or assistance regarding any of the systems described in this notice, contact the CDRH Division of Small Manufacturers Assistance at 1-800-638-2041 or 301-443-6597, or by FAX at 301-443-8818, or write to the contact person above.

Dated: January 13, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-2991 Filed 2-6-95; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

Agency: Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96-511).

1. *Type of Information Collection:* New; *Type of Review Requested:* Regular submission; *Title of Information Collection:* Race and Ethnicity Survey; *Form No.:* HCFA-R-173; *Use:* This is a survey to improve the completeness of race and ethnicity information contained on the Medicare enrollment database; *Respondents:* Individuals or households; *Obligation to Respond:* Voluntary; *Number of Respondents:* 1,800,000; *Total Annual Responses:* 1,800,000; *Total Annual Hours Requested:* 60,000.

Additional Information or Comments: Call the Reports Clearance Office on (410) 966-5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 30, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95-2888 Filed 2-6-95; 8:45 am]

BILLING CODE 4120-03-P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

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 U.S. 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 Robert Benson at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7735 ext 267; fax 301/402-0220). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Polysaccharide-Protein Conjugates

Shouson Szu, Rachel Schneerson, and John B. Robbins (NICHD), Serial No. 07/155,799, Patent Issued 20 Apr 93, U.S. Patent Number 5,204,098.

The invention concerns conjugates of pathogenic microorganism capsular polysaccharides and proteins useful as vaccines. The broadest claim reads: "A composition for enhancing the antibody response of a host comprising a capsular polysaccharide having carboxyl groups conjugated through a thio derivative of said carboxyl groups to a protein in a physiologically acceptable carrier." Applications are pending in Japan and Canada.

The conjugates having capsular polysaccharide from *Staphylococcus* have been exclusively licensed and are not available.

Pertussis Toxin Used as a Carrier Protein With Non-Charged Saccharides in Conjugate Vaccines

Rachel Schneerson, Lily Levi, and John B. Robbins (NICHD), Serial No. 07/932,960, Filed 21 Aug 92.

This invention concerns conjugates of non-charged capsular polysaccharides from pathogenic bacteria with pertussis toxin for use as vaccines. Bacteria having non-charged capsular polysaccharides include *Streptococcus pneumoniae* types 7 and 14. The invention is described in *Infection and Immunity* 60(9), 3528-3532, 1992. Mice injected with Pn14-pertussis toxin conjugates raised serum antibodies against both type 14 capsular polysaccharide and pertussis toxin. Also claimed are methods of synthesis, immunization methods and vaccines. The application has been foreign filed, PCT/US93/07732.

Immunogenic Polysaccharide-Protein Conjugates Containing Poly Alpha (2-8), Alpha (2-9) Neunac Capsular Polysaccharides

Rachel Schneerson, John B. Robbins, and Sarvamangala Devi (NICHD), Filed

12 Mar 91 (priority date), Serial No. 08/153,263 (CON of 07/667,170).

The invention concerns conjugates of *E. coli* K92 capsular polysaccharide and carrier proteins, such as tetanus toxoid. The conjugates have been shown to raise antibodies that react with Group B and Group C *Neisseria meningitidis* and *E. coli* K1 capsular polysaccharides. The conjugate is a potential vaccine against Group B meningitis. Infant rats have been protected from lethal injections of *E. coli* K1 using antisera raised against the conjugates. The invention is described in P.N.A.S. 88, 7175-7179 (1991). Applications are pending in Canada, Australia, Japan and Europe.

Detoxified LPS-Cholera Toxin Conjugate Vaccine for Prevention of Cholera

Shouson Szu, John B. Robbins, and Rajesh K. Gupta (NICHD), Filed 16 Jan 92 (priority date), Serial No. 08/171,188 (CON of 07/821,453).

The invention concerns a conjugate of detoxified lipopolysaccharide (LPS) from *V. cholera* and proteins, potentially useful as a cholera vaccine. The LPS is detoxified by treatment with anhydrous hydrazine, resulting in a detoxified LPS that is less toxic and more immunogenic than cholera LPS's detoxified by other means. The invention has been foreign filed, PCT/US93/00253. In a phase I clinical trial, 38 volunteers were injected with a conjugate of the detoxified LPS and tetanus toxoid. The conjugate vaccines of the invention elicit higher levels of anti-LPS IgG antibodies than whole cell vaccine. IgG can penetrate the intestinal membrane to reach the gut, and, thus, is the primary reason for protection. The serum from the volunteers is vibriocidal for at least nine months; tests are continuing. In the field trials of the whole cell vaccine, protection is correlated with the level of serum vibriocidal antibodies.

Synthesis of Typhoid Fever Vaccine From a Plant or Fruit Polysaccharide

Shouson Szu and Slavomir Bystrisky (NICHD), Filed 17 Oct 94, Serial No. 08/323,918.

The invention is a synthetic *Salmonella typhi* capsular polysaccharide, Vi, made by chemically modifying fruit pectin. The synthetic Vi is useful as a component of a subunit vaccine for typhoid fever. The synthetic Vi is made by acetylating the C₂ and C₃ hydroxyls of the galacturonate subunits of pectin. A vaccine is made by conjugating the synthetic Vi to a carrier protein, such as tetanus toxoid. The synthetic Vi-tetanus toxoid conjugates were shown to react with *S. typhi*

antisera, and when injected into mice raised antibodies reactive with natural *S. typhi* Vi antigen. The conjugates were able to elicit a booster effect. Antibodies or antisera raised against the conjugates and useful for diagnostic purposes and for passive immunization are also part of the invention. The invention is described in *Infection & Immunity* 62, 5545-5549 (1994).

Glucuronoxylomannan-Protein Conjugates of Cryptococcus Neoformans

Sarvamangala Devi, Rachel Schneerson, John E. Bennett, and John B. Robbins (NICHD), Filed 16 Sep 91 (priority date), Serial No. 08/231,444 (CON of 07/760,143).

Cryptococcus neoformans is an encapsulated fungus that causes systemic infections in humans, particularly in those who are immunocompromised. The incidence of infection is high in AIDS patients. The invention concerns conjugates of the glucuronoxylomannan (GXM) capsular polysaccharide of *C. neoformans* and carrier proteins such as tetanus toxoid or cholera toxin. These conjugates are potential vaccines to be given to people at high risk of HIV infection. Another facet of the invention is passive immunization, a therapeutic treatment, using antisera or antibodies raised against the conjugates. Passive protection has been demonstrated in mice. Human clinical trials are ongoing. The basic invention is described in *Infection & Immunity* 59, 3700-3707 (1991).

Dated: January 28, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95-2862 Filed 2-6-95; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Notice of Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of the National Cancer Institute for February, March and April 1995.

These meetings will be open to the public to discuss administrative details or other issues relating to committee activities as indicated in the notice and for the review of concepts being considered for funding. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the