

Dated: July 1, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory
Committee Policy.

[FR Doc. 03-17402 Filed 7-9-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Vaccine For Protection Against *Shigella sonnei* Disease

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in: United States Patent Application 10/346,706 entitled "Vaccine For Protection Against *Shigella Sonnei* Disease" filed on January 15, 2003, to Ardis, Inc., having a place of business in Portola Valley, California. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before September 8, 2003 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: ps193c@nih.gov; Telephone: (301) 435-4646; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION:

Shigellosis is a global human health problem. Transmission usually occurs by contaminated food and water or through person-to-person contact. The bacterium is highly infectious by the oral route, and ingestion of as few as 10 organisms can cause an infection in volunteers. An estimated 200 million people worldwide suffer from shigellosis, with more than 650,000 associated deaths annually. A recent CDC estimate indicates the occurrence of over 440,000 annual shigellosis cases in the United States alone, approximately eighty percent (80%) of which are caused by *Shigella sonnei*.

Shigella sonnei is more active in developing countries. *Shigella* infections are typically treated with a course of antibiotics. However, due to the emergence of multidrug resistant *Shigella* strains, a safe and effective vaccine is highly desirable. No vaccines against *Shigella* infection currently exist. Immunity to *Shigellae* is mediated largely by immune responses directed against the serotype specific O-polysaccharide. Claimed in the invention are compositions and methods for inducing an immunoprotective response against *S. sonnei*. Specifically claimed is an attenuated bacteria capable of expressing a *S. sonnei* antigen comprised of the *S. sonnei* form I O-polysaccharide expressed from the *S. sonnei* rfb/rfc gene cluster. The inventors have shown that the claimed vaccine compositions exhibited one hundred percent (100%) protection against parenteral challenge with virulent *S. sonnei* in mice.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to vaccines against *S. sonnei*.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 2, 2003.

Steven M. Ferguson,

Acting Director, Division of Technology
Development and Transfer, Office of
Technology Transfer.

[FR Doc. 03-17406 Filed 7-9-03; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Vaccine Products for Prevention and Treatment of Chronic Hepatitis C Infections (HCV)

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in:

(1) U.S. Patent No. 6,387,662, issued May 14, 2002, entitled "Synthesis and Purification of Hepatitis C Virus-Like particles" (E-009-1997/0) (Inventors: T. Jake Liang and Thomas F. Baumert (NIDDK)). This application is a continuation of and claims the benefit of priority of International Application No. PCT/US97/05096 filed on March 25, 1997, which claims priority to U.S. patent application No. 60/030,238, filed November 8, 1996.

(2) PCT/US97/05096 filed March 25, 1997, entitled "Synthesis and Purification of Hepatitis C Virus-Like particles in vitro" (related to E-009-1997/0) (Inventors: T. Jake Liang and Thomas F. Baumert (NIDDK)), National Stage filed in Australia (Patent No. 738585, issued January 03, 2002), the European Union (European Patent Office Patent Application Number 9791652.6), Canada (Patent Application Number 2269097), and in Japan (Patent Application Number 10-522521). to Virionics Corporation, having a place of business in Odenton, Maryland. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before September 8, 2003 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: ps193c@nih.gov; Telephone: (301) 435-4646; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: The technology relates to production of