

This guidance for industry represents the agency's current thinking on scale-up and post approval equipment changes for immediate release solid oral dosage forms regulated by CDER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain copies of "SUPAC-IR: Immediate Release Solid Oral Dosage Forms—Manufacturing Equipment Addendum" by using the World Wide Web (WWW) and going to "http://www.fda.gov/cder/guidance/index.htm".

Dated: October 14, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-27738 Filed 10-20-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.
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 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 contacting George Keller, Ph.D., Technology Licensing Specialist, at the Office of Technology Transfer, National Institutes of Health, 6011 Executive

Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057, ext. 246; fax: 301/402-0220; e-mail: KellerG@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Diagnostic Reagents and Vaccines for Multiple Genotypes of Hepatitis C Virus

J Bukh, RH Miller, RH Purcell (NIAID)
Serial Nos. 08/466,601 and 08/468,570
filed 06 Jun 95 (DIV of U.S. Patent
5,514,539 issued 07 May 96)

The invention describes the complete nucleotide and deduced amino acid sequences of the envelope 1 (E1) gene of 51 hepatitis C virus (HCV) isolates from around the world and the grouping of these isolates into twelve distinct HCV genotypes. More specifically, this invention relates to the oligonucleotides, peptides and recombinant proteins derived from the envelope 1 gene sequences of these isolates and to diagnostic methods and vaccines that employ these reagents.

Antigenic Protein of *Borrelia burgdorferi*

WJ Simpson, TG Schwan (NIAID)
Serial No. 08/396,957 filed 01 Mar 95
(DIV of U.S. Patent 5,470,712 issued
28 Nov 95)

This patent application describes a 39 kDa protein (P39) that is species-specific and expressed by all North American and European *B. burgdorferi* isolates. The discovery includes the cloning and expression of the gene for P39 in *E. coli* and the use of P39 as a diagnostic antigen for the serodiagnosis of Lyme borreliosis. The P39 described in this invention report has been found not only to be species-specific, but reactive only with human Lyme borreliosis sera. This suggests that any patient's serum that is shown to react to P39, irrespective of the patient's clinical picture, can be diagnosed as having or having had Lyme borreliosis.

Versatile Reagent for Detecting Murine Leukemia Viruses

LH Evans, WJ Britt (NIAID)
Serial No. 08/046,352 filed 08 Apr 93

Monoclonal antibodies directed at the proteins of murine leukemia viruses (MuLVs) have some value as immunological reagents, but differ greatly in their applicability. The kit described in this invention uses a monoclonal antibody designated 83A25, which identifies almost all ecotropic, xenotropic, polytropic, and amphotropic MuLVs. It can be used in a wide variety of procedures, including focal immunofluorescence assays on

live or fixed monolayers, immunoblotting, immunoprecipitation, immunohistochemical, and flow cytometric procedures. This kit overcomes some of the problems associated with prior methods, which may not effectively precipitate proteins or react in immunoblots, are not capable of detecting MuLVs belonging to all classes with a single reagent, and may not efficiently neutralize all MuLVs.

Dated: October 7, 1997.

Barbara M. McGarey, J.D.

Deputy Director, Office of Technology
Transfer.

[FR Doc. 97-27864 Filed 10-20-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Therapeutic Strategies for Papillomavirus (Telephone Conference Call).
Date: October 29, 1997.

Time: 2:00 p.m. to Adjournment.

Place: Teleconference, 6003 Executive Boulevard, Solar Building, Room 1A1, Bethesda, MD 20892, (301) 402-0747.

Contact Person: Dr. Sayeed Quraishi, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C22, Bethesda, MD 20892, (301) 496-7465.

Purpose/Agenda: To evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: October 15, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-27860 Filed 10-20-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Dental Research; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Dental Research Special Emphasis Panel (SEP) meetings:

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R03 grant (98-14).

Dates: November 5, 1997.

Time: 2:00 p.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. Philip Washko, Scientist Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R44 grant (98-12).

Dates: November 12, 1997.

Time: 10:00 a.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. Philip Washko, Scientist Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R03 grant (98-08).

Dates: November 17, 1997.

Time: 2:30 p.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. Philip Washko, Scientist Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R03 grant (98-13).

Dates: November 20, 1997.

Time: 12:00 noon.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. Philip Washko, Scientist Review Administrator, 4500 Center

Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research)

Dated: October 15, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-27861 Filed 10-20-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting of the Deafness and Other Communication Disorders Programs Advisory Committee

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Deafness and Other Communication Disorders Programs Advisory Committee.

Date: November 3, 1997.

Place: National Institutes of Health, 9000 Wisconsin Avenue, Building 31C, Conference Room 7, Bethesda, MD 20892.

Time: 8 am to 4:30 pm.

Purpose/Agenda: To hold discussions on Extramural Research programs.

Contact Person: Ralph F. Naunton, M.D., Director, Division of Human Communication, NIH/NIDCD, 6120 Executive Boulevard, MSC 7180, Bethesda, MD 20892-7180, 301-496-1804.

The entire meeting will be open to the public, with attendance limited to space available. A summary of the meeting and a roster of the members may be obtained from Dr. Naunton's office. For individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodation, please contact Dr. Naunton prior to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: October 15, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-27862 Filed 10-20-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Research on Women's Health; Notice of Meeting—"Beyond Hunt Valley: Research on Women's Health for the 21st Century"

Notice is hereby given that the Office of Research on Women's Health (ORWH), Office of the Director, National Institutes of Health (NIH), will convene a meeting on November 17, 18, and 19, 1997, at the Bethesda Marriott (formerly Pooks Hill Marriott), Bethesda, Maryland.

The NIH/AES is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical educations for physicians.

The NIH/AES designates this educational activity for a maximum of 10 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

The ORWH/NIH research agenda recognizes the full spectrum of research from basic to clinical research and trials, epidemiological and population studies, clinical applications and health outcomes. Since September 1996, the ORWH has convened a series of three regional meetings for the purpose of updating the NIH scientific agenda on women's health research to meet the challenges of a changing scientific and social world. This mechanism provides an opportunity for the continued collaboration between individuals and groups of women and their families, advocates, scientists, health care practitioners and public health policy makers with the NIH to update and revise the national research agenda for women's health into the twenty-first century. The purpose of this national meeting will be to culminate the dialogue conducted over the last year to update and revise the current biomedical research agenda for women's health, as originally presented in the Report of the National Institutes of Health; Opportunities for Research on Women's Health, a publication based on a conference held in Hunt Valley, Maryland, September 1991.

The first day of the national meeting, November 17, will be devoted to receiving public testimony from 1:00 p.m. to 6:00 p.m. The ORWH invites individuals or individuals representing organizations with an interest in research areas related to women's health