Agenda: On November 13, 1997, the committee will discuss new drug application (NDA) 20–788, Propecia™ (finasteride 1 milligram tablets, Merck Research Laboratories), for treatment of androgenetic alopecia to increase hair growth and to prevent further hair loss. On November 14, 1997, the committee will participate in a scientific discussion of clinical trial design questions for products intended for the treatment of burn wounds. This is one segment of an overall effort by the agency to develop a guidance document on wound healing products.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 4, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m., and between approximately 1 p.m. and 1:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 4, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27816 Filed 10–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 17, 1997, 8:30 a.m. to 4:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: John C. Monahan, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss general issues and vote on an original premarket approval application (PMA) for an ultrasound bone sonometer and an original PMA for a breast impedance scanner.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 10, 1997. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 10, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 10, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27817 Filed 10–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0349]

Guidance for Industry on SUPAC–IR: Immediate Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Level 1 guidance for industry entitled ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Manufacturing Equipment Addendum.'' This guidance is intended to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and abbreviated antibiotic applications (AADA's) who wish to change equipment during the postapproval period. This guidance document represents the agency's current thinking on scale-up and postapproval equipment changes (SUPAC) for immediate release dosage forms regulated by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–623), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Manufacturing Equipment Addendum.'' This guidance is intended to provide recommendations to pharmaceutical manufacturers using CDER'S Guidance for Industry on ''Immediate Release Solid Oral Dosage Forms, Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (SUPAC–IR), which was issued in November 1995. The manufacturing equipment addendum may be used in conjunction with the SUPAC–IR guidance in determining what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations in sections V and VI.A of the SUPAC–IR guidance.

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)