Dated: October 23, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–28599 Filed 10–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biologics License Application for Blood Products, and Reporting Changes to an Approved Application; Public Workshop

AGENCY: Food and Drug Administration.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Workshop on the Biologics License Application (BLA) for Blood Products, and Reporting Changes to an Approved Application.'' The topics to be discussed include completing Form FDA 356h; chemistry, manufacturing, and controls information; establishment information; changes requiring supplement submission and approval; changes requiring supplement submission at least 30 days prior to distribution; changes to be described in an annual report; and comparability protocols.

Date and Time: The workshop will be held on December 2, 1997, 8:30 a.m. to 5 p.m.

Location: The workshop will be held at Jack Masur Auditorium, National Institutes of Health, 8800 Rockville Pike, Bldg. 10, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION: The public workshop is intended for firms which manufacture or intend to manufacture licensed human blood products, including products for transfusion and source materials for further manufacture. The workshop is also intended for firms planning to supplement their current license for additional products or modifications to current products.

The goals for the workshop are to provide guidance on the application procedures, forms, and documentation needed for the single BLA and guidance on how changes to approved applications are to be reported to the FDA.

Registration: Early registration is recommended on or before Friday, November 21, 1997. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Michelle Priester Healy, Conference Management Associates, Inc., 1010 Wayne Ave., suite 450, Silver Spring, MD 20910, 301–585–8203, FAX 301–585–1186, e-mail confmgmtmd@aol.com. Registration at the site will be done on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Michelle Priester Healy at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: October 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28671 Filed 10–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97P–0220]

Determination That Pseudoephedrine Hydrochloride 120-Milligram Extended-Release Capsules Over-the-Counter Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that pseudoephedrine hydrochloride (Sudafed 12-Hour Capsules) 120-milligram (mg) extended-release capsules over-the-counter (OTC) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for pseudoephedrine hydrochloride 120-mg extended-release capsules.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated June 3, 1997, and an amendment dated June 24, 1997 (Docket Nos. 97P–0220/CP1 and 97P–0220/AMD1), submitted under 21 CFR 10.30 and 314.161(a)(3), Eurand America, Inc., requested that the agency determine whether pseudoephedrine hydrochloride 120-mg extended-release capsules (OTC) were withdrawn from sale for reasons of safety or effectiveness. Pseudoephedrine hydrochloride 120-mg extended-release capsules, OTC (Sudafed 12-Hour Capsules) were the subject of approved NDA 17–941 held by Burroughs Wellcome Co. Burroughs Wellcome

notified FDA in writing that Sudafed 12-Hour Capsules (pseudoephedrine hydrochloride 120-mg extended-release capsules, OTC) were no longer being marketed under NDA 17–941 and requested that approval of the application be withdrawn. In the **Federal Register** of September 29, 1995 (60 FR 50626), FDA withdrew approval of NDA 17–941.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that pseudoephedrine hydrochloride 120-mg extended-release capsules (OTC) were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain pseudoephedrine hydrochloride 120-mg extended-release capsules (OTC) in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to pseudoephedrine hydrochloride 120-mg extended-release capsules (OTC) may be approved by the agency.

Dated: October 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28672 Filed 10–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Endocrinologic and Metabolic Drugs 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 19 and 20, 1997, 8 a.m. to 5 p.m., and on November 21, 1997, 8 a.m. to 3 p.m.

Location:

November 19, 1997: Bethesda Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

November 20 and 21, 1997: Holiday Inn Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 19, 1997, the committee will discuss new drug application (NDA) 20–741, Prandin™ or Actulin™ (repaglinide, Novo Nordisk) for the treatment of type 2 diabetes in patients whose hyperglycemia cannot be controlled satisfactorily by diet and exercise alone. On November 20, 1997, the committee will discuss NDA 20–815, Evista™ (raloxifene hydrochloride, Eli Lilly and Co.) for the prevention of postmenopausal osteoporosis. On November 21, 1997, the committee will meet in closed session to permit discussion and review of trade secret and/or confidential information.

Procedure: On November 19 and 20, 1997, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 14, 1997. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on November 19 and 20, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 14, 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.

Closed Committee Deliberations: On November 21, 1997, 8 a.m. to 3 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The investigational new drug (IND) and Phase I and II drug products in process will be presented and recent action on selected NDA's will be discussed.

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

Dated: October 22, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–28556 Filed 10–28–97; 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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Identification of a Viral Etiology for B-Precursor Acute Lymphoblastic Leukemia of Childhood

MA Smith (NCI)
Serial No. 60/036,991 filed 30 Jan 97
Licensing Contact: Joseph Contrera, 301/496–7056 ext. 244.

The present invention claims that the possible etiologic agent for some cases of acute lymphoblastic leukemia (ALL) in children is JC virus (a human polyomavirus), and that infection in utero can lead to subsequent development of ALL during childhood. JC virus was identified as a possible etiologic agent based on specific properties associated with the virus, including: (1) Specificity for B-lymphocytes as compared to T-lymphoctyes; (2) the ability to induce genomic instability via its T antigen, which interacts with cellular p53; and (3) epidemiological data showing concordance between the frequency of ''susceptible'' (i.e. previously not exposed to JC virus and therefore