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capsules, OTC) were no longer being marketed under NDA 17–941 and requested that approval of the application be withdrawn.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and 314.162(c), has determined that pseudoephedrine hydrochloride 120-mg extended-release capsules (OTC) were not withdrawn from sale for reasons of safety or effectiveness.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