contained on pages 7 through 9 of the PHS 2590 (Rev. 5/95) form should be followed for reporting on research progress. Supplemental reporting instructions may be required depending on different FDA grant program requirements. After reviewing the noncompeting continuation application, the FDA program and/or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information in a timely manner may result in a delayed award.

FDA grants are funded under the legislative authority of section 301 of the Public Health Service Act (24 U.S.C. 241).

Dated: August 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20851 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 96P–0190/CP1, 96P–0197/CP1, 96P–0251/CP1]

Determination That Selegiline Hydrochloride 5-Milligram Tablet Was Not Withdrawn From Sale For Reasons of Safety or Effectiveness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and Drug Administration (FDA) has determined that selegiline hydrochloride (Eldepryl®) 5-milligram (mg) tablet was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for selegiline hydrochloride 5-mg tablet.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 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 (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 (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.

Selegiline hydrochloride (Eldepryl®) 5-mg tablet is the subject of approved NDA 19–334, held by Somerset Pharmaceuticals, Inc. (Somerset). On May 17, 1996, Somerset withdrew the selegiline hydrochloride 5-mg tablet from sale, and began marketing in its place a capsule form of selegiline hydrochloride 5-mg (NDA 20–647).

On June 12, 1996, Novopharm Ltd. submitted under 21 CFR 10.30 a citizen petition (Docket No. 96P–0190/CP1) regarding the status of the selegiline hydrochloride 5-mg tablet. Two similar citizen petitions were subsequently received by the agency; a petition by Endo Laboratories, L.L.C. was filed on June 17, 1996 (Docket No. 96P–0197/CP1), and a petition submitted by Williams & Connolly on behalf of Alphapharm, Ltd. was filed on July 10, 1996 (Docket No. 96P–0251/CP1). The three petitions request that the agency determine whether the selegiline hydrochloride 5-mg tablet was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, keep the drug listed in the Orange Book.

The agency has reviewed its records and under § 314.161, has determined that the selegiline hydrochloride 5-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. In reaching its decision, FDA considered comments submitted by Somerset, in which Somerset asserted that the drug was withdrawn from sale for safety reasons. Somerset requested that FDA deny the citizen petitions.

Somerset claims that Eldepryl® 5-mg tablet was withdrawn from the market ''out of concern for the safety of patients with Parkinson's Disease.'' First, it refers to the appearance of counterfeit Eldepryl® tablets in the U.S. marketplace. This is not a problem unique to Eldepryl® and is not evidence that the product is unsafe.

Second, Somerset makes a nonspecific reference to ''the information contained in NDA # 19–334'' as confirmation that the removal of the tablet form of the drug was out of concern for the safety of patients. FDA's examination of this NDA found no evidence to support this claim. Somerset may have been alluding to reports of difficulty swallowing tablets in patients with Parkinson's Disease. That some patients may prefer an alternative dosage form is common with oral products regardless of the disease being treated. FDA does not regard providing a second dosage form that some patients may find more convenient than the first as evidence that the first is unsafe. Somerset may also have been alluding to reports of confusion between Eldepryl® tablets and enalapril. This is not a safety concern relevant to generic products because, among other reasons, they would not use the name Eldepryl® .

The agency concludes that Eldepryl® tablets were withdrawn from sale for reasons other than for safety or effectiveness. Accordingly, the agency will maintain selegiline hydrochloride 5-mg tablet 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 selegiline hydrochloride 5-mg tablet may be approved by the agency.

Dated: August 9, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20857 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0274]

Summit Technology, Inc.; Premarket Approval of SVS Apex (Formerly the Omnimed) Excimer Laser System for Photorefractive Keratectomy (PRK)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Summit Technology, Inc., Waltham, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the SVS Apex (formerly the OmniMed) Excimer Laser System. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 20, 1995, of the approval of the application.

DATES: Petitions for administrative review by September 16, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Debra Y. Lewis, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–3623.

SUPPLEMENTARY INFORMATION: On October 12, 1993, Summit Technology, Inc., Waltham, MA 02154, submitted to CDRH an application for premarket approval of the SVS Apex (formerly the OmniMed) Excimer Laser System. The excimer laser in the Systems delivers pulses at 193 nm wavelength. The excimer laser is indicated for a 6.0 mm ablation zone photorefractive keratectomy (PRK) in subjects with 1.5 to 7.0 diopters of myopia and astigmatism ≤ 1.5 diopters. On October 20, 1995, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended conditional approval of the application. The concerns of the panel have been adequately addressed by Summit Technology, Inc. in subsequent submissions to FDA. On October 20, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before September 16, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 1, 1996.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–20855 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month September 1996:

Name: Council on Graduate Medical Education.

Date and Time: September 11, 1996, 8:30 a.m.–5:00 p.m.; September 12, 1996, 8:30 a.m.–4:00 p.m.

Place: Omni Shoreham Hotel, Empire Room, 2500 Calvert Street, NW., Washington, DC 20008.

This meeting is open to the public.

Agenda: The agenda will include discussion, reports and recommendations in the following areas: minorities in medicine; geographic distribution/medical education consortia; physician competencies in managed care; and IMG entry and participation in the physician workforce.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443–6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Health Resources and Service Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: July 9, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96–20820 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Center for Research Resources; Notice of Meeting of the National Advisory Research Resources Council and Its Planning Subcommittee

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Research Resources Council (NARRC), National Center for Research Resources (NCRR). This meeting will be open to the public as indicated below. Attendance by the public will be limited to space available.

This meeting will be closed to the public as indicated below in accordance with provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or