appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of any person subject to this notice to file a timely written notice of appearance and request for hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug product(s). Any new drug product marketed without an approved new drug application is subject to regulatory action at any time, but any person subject to this notice who files a timely written notice of appearance and request for hearing and who remains a party to this proceeding will not be subject to regulatory action for matters covered by this notice until the conclusion of this proceeding. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact to justify a hearing, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address 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. 502, 505, 21 U.S.C. 352, 355) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.100).

Dated: April 4, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–9065 Filed 4–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98N–0718 and 76N–0377]

Pharmacia & Upjohn et al.; Withdrawal of Approval of One New Drug Application and Four Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of one new drug application (NDA) and four abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: May 14, 2003.

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

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 17–968	Depo-Testadiol (testosterone cypionate and estradiol cypionate) Injection, 50 milligrams/milliliter (mg/mL) and 2 mg/mL.	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199.
ANDA 85–603	Testosterone Cypionate-Estradiol Cypionate Injection.	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4706.
ANDA 85–860	Testosterone Enanthate and Estradiol Valerate Injection, 180 mg/mL and 8 mg/mL.	Do.
ANDA 85–865	Testosterone Enanthate and Estradiol Valerate Injection, 90 mg/mL and 4 mg/mL.	Do.
ANDA 86–423	Ditate-DS (testosterone enanthate and estradiol valerate) Injection, 180 mg/mL and 8 mg/mL.	Savage Laboratories, 60 Baylis Rd., Melville, NY 11747.

The applications listed in the table in this document, all estrogen-androgen combination products, were submitted following a finding by the FDA published in the **Federal Register** of September 29, 1976 (41 FR 43112). Elsewhere in today's issue of the **Federal Register**, FDA is initiating a proceeding in which it proposes to amend the 1976 notice. That proceeding will determine if there is substantial evidence of effectiveness of the estrogen-androgen combination products specifically named in the notice proposing to amend the 1976 notice, as well as of any products that are identical, related, or similar (including but not limited to the five products listed in this notice). The agency, therefore, is deferring until the outcome of that proceeding the determination, under § 314.161 (21 CFR 314.161), of whether the five products listed in this notice were withdrawn for reasons of safety or effectiveness.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective May 14, 2003.

Dated: April 4, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–9064 Filed 4–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral 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). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

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

Date and Time: The meeting will be held on May 13 and 14, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: *TurnerT@cder.fda.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 13, 2003, the committee will discuss new drug applications (NDA) 21–567 and 21–568, REYATAZ (atazanavir sulfate) capsules and powder for oral use, Bristol-Myers Squibb Co., proposed for the treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents. On May 14, 2003, the committee will discuss supplemental new drug application (SNDA) 20–550/S–019, VALTREX (valacyclovir hydrochloride) caplets, GlaxoSmithKline, proposed for reduction of the risk of transmission of genital herpes with the use of suppressive therapy.

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 May 6, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 13, 2003, and between approximately 11 a.m. and 12 noon on May 14, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 6, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tara Turner at least 7 days in advance of the meeting.

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

Dated: April 7, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9031 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System 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). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

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

Date and Time: The meeting will be held on May 16, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD, 301–652–2000.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e–mail: *SomersK@cder.fda.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12543. Please call the Information Line for up to date information on this meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 20–690, supplement SE1–020, ARICEPTR (donepezil hydrochloride tablets), Eisai Medical Research Inc., indicated for the treatment of vascular dementia. The background material will become available no later than the day before the meeting and will be posted under the Peripheral and Central Nervous System Drugs Advisory Committee docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2003 and scroll down to the Peripheral and Central Nervous System Drugs Advisory Committee meetings.)

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 May 9, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 9, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Templeton-Somers at least 7 days in advance of the meeting.