

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.

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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.