

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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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: [Insert date 30 days after date of publication in the FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT:

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Food and Drug Administration,  
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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 51 <sup>st</sup> 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	Ditrate-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 [insert date 30 days after date of publication in the FEDERAL REGISTER].

Dated: April 4, 2003.

Janet Woodcock,

Director, Center for Drugs Evaluation and Research.

[FR Doc. 03-????? Filed ??-??-03; 8:45am]

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