

[Docket No. FDC-D-450; NDA Nos. 16-048, 16-753]

**ELI LILLY AND CO.**

**C-Quens Tablets and Estalor-21 Tablets; Notice of Withdrawal of Approval of New-Drug Applications**

Eli Lilly and Co., Indianapolis, Ind. 46206, holder of the following new-drug applications for products not being marketed, has waived opportunity for hearing and agreed to the withdrawal of approval of the new-drug applications.

1. NDA No. 16-048 for C-Quens Tablets which provide a dosage regimen consisting of two different tablets, one containing 80 mcg. mestranol per tablet and the other containing 80 mcg. mestranol in combination with 2 mg. chlormadinone acetate. The applicant discontinued the marketing of this product.

2. NDA No. 16-753 for Estalor-21 Tablets which provide a dosage regimen consisting of two different tablets, one containing 100 mcg. mestranol in one tablet and the other containing 100 mcg. mestranol in combination with 1.5 mg. chlormadinone acetate. The applicant has never marketed this product.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505 (e), 52 Stat. 1053 as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120) finds that studies in dogs have shown an increased incidence of mammary tumors resulting from the chlormadinone acetate component; that while these findings were not directly applicable to the human and there was no evidence of increase in the frequency of mammary tumors in women using the drug, the findings raised a safety question and Eli Lilly and Co., discontinued the manufacture of the drug in October 1970.

Therefore, pursuant to the foregoing findings, approval of the above new-drug applications, and all amendments and supplements thereto, is withdrawn effective on the date of publication of this document (3-16-72).

Dated: March 8, 1972.

R. E. DUGGAN,  
Acting Associate Commissioner  
for Compliance.  
[FR Doc.72-3955 Filed 3-15-72; 8:52 am]

[Docket No. FDC-D-451; NDA No. 14-412]

**UPJOHN CO.**

**Provest Tablets; Notice of Withdrawal of Approval of New-Drug Application**

The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49001, holder of new-drug application No. 14-412 for Provest Tablets containing 10 mg. medroxyprogesterone acetate and 0.05 mg. ethinyl estradiol, has discontinued marketing of the product, waiving opportunity for hearing, and agreed to withdrawal of approval of the new-drug application.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal

Food, Drug, and Cosmetic Act (sec. 505 (e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that studies in dogs have shown an increased incidence of mammary tumors resulting from the medroxyprogesterone acetate component; that while these findings were not directly applicable to the human and there was no evidence of increase in the frequency of mammary tumors in women using the drug, the findings raised a safety question and The Upjohn Co. discontinued the manufacture of the drug in October 1970.

Therefore, pursuant to the foregoing finding, approval of new-drug application No. 14-412, including all amendments and supplements thereto, is hereby withdrawn effective on the date of publication of this document (3-16-72).

Dated: March 8, 1972.

R. E. DUGGAN,  
Acting Associate Commissioner  
for Compliance.

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