

DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE

Food and Drug Administration  
[DESI 740; Docket No. FDC-D-360;  
NDA 4-039, etc.]

CERTAIN ESTROGENS FOR ORAL USE  
Notice of Withdrawal of Approval of New  
Drug Applications

A notice was published in the FEDERAL REGISTER of September 26, 1973 (38 FR 26825) extending to the firms named below and any interested person an opportunity for hearing on the proposal of the Commissioner of Food and Drugs to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act to withdraw approval of pertinent parts of the listed new drug applications. The basis of the proposed action was that the drugs in the described strengths are not shown to be safe for use for their labeled indications.

NDA's 4-039 and 4-041: Those parts of the NDA's providing for Diethylstilbestrol Tablets and Enseals containing 1 mg. diethylstilbestrol; Eli Lilly and Co., Post Office Box 613, Indianapolis, IN 46206.

NDA 6-603: Those parts of the NDA providing for a tablet containing 25 mg. diethylstilbestrol; Rexall Drug Company, 3901 North Kingshighway, St. Louis, MO 63115.

NDA 4-056: Those parts of the NDA providing for tablets containing 25 and 100 mg. diethylstilbestrol; E. R. Squibb and Sons, Lawrenceville-Princeton Road, Post Office Box 4000, Princeton, N.J. 08540.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new

drug application(s) reviewed and are subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (HFD-300), 5600 Fishers Lane, Rockville, Maryland 20852.

Neither the holders of the applications nor any other person filed a written appearance of election within the 30 days provided by said notice. The failure to file such an appearance constitutes election by such persons not to avail themselves of an opportunity for hearing.

The Director of the Bureau of Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended; 21 U.S.C. 355), and under the authority delegated to him (21 CFR 2.121) finds that on the basis of new information before him with respect to the drugs, evaluated together with the evidence available to him at the time of approval of the applications, the drug products are not shown to be safe for use under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, pursuant to the foregoing finding, approval of those parts of NDA's 4-039, 4-041, 4-056, and 6-603 providing for the products described above, and all amendments and supplements applying thereto, is withdrawn effective on February 18, 1975.

Shipment in interstate commerce of the above-listed drug products or of any identical, related, or similar product, not the subject of an approved new drug application, will then be unlawful.

Dated: September 16, 1974.

J. RICHARD CROUT,  
Director, Bureau of Drugs.

[FR Doc. 75-3200 Filed 2-4-75; 8:45 am]

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[DESI 740: Docet No. FDG 1-1-71 NDA  
4-030, etc.]

**CERTAIN ESTROGENS FOR ORAL OR  
PARENTERAL USE**

**Opportunity for Hearing on Proposal To  
Withdraw Approval of New Drug Applica-  
tions**

In a notice (DESI 740) published in the FEDERAL REGISTER of November 10, 1971 (36 FR 21537), the Commissioner of Foods and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group concerning certain orally and parenterally administered estrogens. Appearing elsewhere in this issue of the FEDERAL REGISTER is a followup notice describing the conditions under which certain of those products are regarded to be effective:

The following new drug applications referenced in the notice provide for oral dosage forms containing 25 mg. or more of diethylstilbestrol and a parenteral dosage form (1 ml. ampule) containing 1 mg. of diethylstilbestrol. Such single dosages of diethylstilbestrol are regarded as either contraindicated (e.g., for accidents of pregnancy), and/or are in excess of the amounts recognized as appropriate for the indications claimed in the labeling reviewed by the Academy, thus raising a question of safety for use for the indications claimed.

NDA's 4-030 and 4-041: Those parts of the NDA's providing for Diethylstilbestrol Tablets and Enseals containing 25 mg. diethylstilbestrol; Eli Lilly and Co., Post Office Box 618, Indianapolis, IN 46206.

NDA 6-603: Those parts of the NDA providing for a tablet containing 25 mg.

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diethylstilbestrol; Rexall Drug Company, 291 North Kingshighway, St. Louis, MO 15.

NDA 4-956: Those parts of the NDA providing for tablets containing 25 and 100 mg. diethylstilbestrol; E. R. Squibb and Sons, Lawrenceville-Princeton Road, Post Office Box 4090, Princeton, N.J. 08540.

NDA 7-244: Diethylstilbestrol Ampoules (1 ml.), containing 25 mg. diethylstilbestrol in ethyl oleate; Eli Lilly and Co. This dosage form had been labeled only for use in certain types of accidents of pregnancy. Lilly discontinued this product in 1966 and approval of the NDA was withdrawn February 3, 1972 (37 FR 2051), on grounds that the applicant had failed to make reports under section 505(j) of the Act (21 U.S.C. 355(j)) and (120.12 or 120.35(e) and (f) of the new drug regulations (21 CFR 120.12 and 120.35). In view of that, this product is included in this notice only for the purpose of informing interested persons of the conclusions reached in the Drug Efficacy Study concerning it.

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of pertinent parts of the listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s) shows that the drugs are not shown to be safe for use under the conditions of use prescribed, recommended, or suggested in the labeling.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed. See 21 CFR 130.40 (37 F.R. 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5630 Fishers Lane, Rockville, Maryland 20852.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 120), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

On or before October 26, 1973, the applicant(s) and any other interested person is required to file with the Hearing

Clerk, Food and Drug Administration, Room 9-30, 5630 Fishers Lane, Rockville, Maryland 20852, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election within the specified time will constitute an election by him not to avail himself of the opportunity for a hearing. No extension of time may be granted.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of pertinent parts of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, on or before October 26, 1973, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 120.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that the drugs are safe for use for the labeling claims involved, the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after October 26, 1973, a written notice of the time and place at which the hearing will commence. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and or elections not to request a hearing may be seen in the Office of the Hearing Clerk

(address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1932-33 as amended; 21 U.S.C. 355) and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated September 12, 1973.

A. M. SCHMIDT,  
Commissioner of Food and Drugs.  
[FR Doc.73-20443 Filed 9-21-73; 3:45 am]

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