

NOTICES

NDA No.	Drug name	Applicant and address
11-352	Dialose Plus Capsules (oxyphenisatin acetate, dioctyl sodium sulfosuccinate and sodium carboxymethylcellulose).	The Stuart Co., Division of Atlas Chemical Industries, Inc., 380 East Foot-hill Blvd., Pasadena, CA 91109.
10-982	Noloc Capsules (oxyphenisatin acetate and dioctyl sodium sulfosuccinate).	Dumas-Wilson and Co., Division Mal-linckrodt Chemical Works, 3600 North Second St., St. Louis, MO 63147.
10-732	Isadoxol Tablets (oxyphenisatin acetate and dioctyl sodium sulfosuccinate).	G. F. Harvey Co., Inc., 9-101 Saw Mill River Rd., Yonkers, NY 10701.
11-040	Ocervlan Compound Tablets (oxyphenisatin acetate, dioctyl potassium sulfosuccinate, and methylcellulose).	Don Baxter, Inc., 1015 Grandview Ave., Glendale, CA 91201.

tions Nos. 10-732, 10-982, and 11-352 and all amendments and supplements applying thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (2-1-72).

Dated: January 21, 1972.

SAM D. FINE

Associate Commissioner

[FR 10-7-72]

In addition to the above-listed drugs, all of which involve oxyphenisatin acetate and are for oral use, the notice of September 30, 1971, also included two rectally administered drugs containing oxyphenisatin base (NDA's 11-370 and 12-587). In response to the notice, information concerning the rectally administered drugs has been received and is being reviewed. Upon completion of that review, the Commissioner's conclusions concerning rectally administered oxyphenisatin base will be published in the FEDERAL REGISTER.

The Stuart Co., holder of NDA 11-352, by letter of November 4, 1971, has waived the opportunity for a hearing, advising that the preparation in question no longer contains oxyphenisatin acetate.

Mallinckrodt Chemical Works, by letter of October 7, 1971, has waived the opportunity for a hearing concerning NDA 10-982, stating that marketing of the drug was discontinued in 1968.

Neither G. F. Harvey Co., Inc., holder of NDA 10-732, nor any other interested person, has filed a written appearance of election concerning that NDA as provided by said notice. The failure to file such an appearance is construed as an election by such persons not to avail themselves of the opportunity for a hearing.

Approval of NDA 11-040, held by Don Baxter, Inc., was withdrawn August 6, 1971 (36 F.R. 14493), along with a large number of others involving drugs which had been discontinued or never marketed.

The Commissioner of Food and Drugs, pursuant to the 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 new evidence of clinical experience, not contained in the new drug applications or not available to the Commissioner until after the applications were approved, evaluated together with the evidence available to him when the applications were approved, reveals that the drugs are not shown to be safe for use under the conditions of use upon the basis of which the applications were approved.

Therefore, pursuant to the foregoing finding, approval of new-drug applica-

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Food and Drug Administration

(DESI 10732; Docket No. FDC-D-255; NDA 10-732 etc.)

CERTAIN DRUGS CONTAINING
OXYPHENISATIN ACETATE

Notice of Withdrawal of Approval of
New Drug Applications

On September 30, 1971, there was published in the FEDERAL REGISTER (36 F.R. 19184) a notice of opportunity for hearing (DESI 10732) in which the Commissioner of Food and Drugs proposed 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 the following new drug applications, on the grounds that the drugs are not shown to be safe for use under the conditions of use upon the basis of which the applications were approved: