In the United States District Court for the Western District of Michigan
Southern Division

UNITED STATES OF AMERICA

v.

THE UPJOHN COMPANY, A CORPORATION

No. ———

21 U.S.C. 331 and 333

COUNT I

The United States Attorney charges:

That on or about August 26, 1965 the Upjohn Company, a corporation, organized and existing under the laws of the state of Delaware and trading and doing business at Kalamazoo, Michigan, the defendant herein, did, within the Southern Division of the Western District of Michigan, in violation of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(a)], unlawfully cause to be introduced and delivered for introduction into interstate commerce at Kalamazoo, Michigan for delivery to Cleveland, Ohio consigned to the Upjohn Company warehouse at 1740 Chester Avenue, Cleveland, Ohio, a number of bottles containing a drug designated by the name "Orinase";

That displayed upon each of said bottles was certain labeling which consisted, among other things, of the following printed and graphic matter:

200 Tablets No. 5849, Orinase (tolbutamide) 0.5 Gm. Each tablet contains Tolbutamide . . . 0.5 Gm. Caution: Federal law prohibits dispensing without prescription. The Upjohn Company, Kalamazoo, Michigan.

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(f)(1) in that its labeling failed to bear adequate directions for use and it was not exempt from such requirement since it was a prescription drug which was a new drug subject to 21 U.S.C. 355 and its labeling, namely, the monograph relating to said drug set forth in the 1965 Edition of the Physician's Desk Reference, was not, as required by regulations, 21 CFR 1.106(b)(4)(1), substantially the same as the labeling authorized by the approved new drug application effective with respect to said drug.

HAROLD D. BEATON,
United States Attorney.

In The United States District Court for The Eastern District of New York

No. 66–M–163

UNITED STATES OF AMERICA, LIBELANT

v.

WARNER-LAMBERT PHARMACEUTICAL COMPANY, *Claimant*

An article of drug consisting of 68 bottles, more or less, of an article labeled in part: "100 80 mg. Tablets Peritrate SA Sustained Action (pentaerythritol tetranitrate) (Warner-Chilcott Laboratories Div., Morris Plains, N.J.)"

DECREE

On the 28th day of February, 1966, a Libel of Information against the above-described article was filed in this Court on behalf of the United States of America by the United States Attorney and the Assistant United States Attorney for this District. The Libel alleges that the article, namely 68 bottles of Peritrate SA, proceeded against is a drug which was shipped in interstate commerce and is in violation of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(a) and 21 U.S.C. 352(a), 352(f)(1) and 352(n)].

Pursuant to monition issued by this Court, the United States Marshal for this District seized said article on the 28th day of February, 1966. Thereafter, Warner-Lambert Pharmaceutical Company of Morris Plains, New Jersey, intervened and