

of said Act, 21 U.S.C. 352(a), in that it is a prescription drug offered and distributed for sale in the State of Illinois, and the advertisements for said drug appearing in the February, 1967, and April, 1967, issues of the *American Journal of Psychiatry* and in the February, 1967, issue of the journal, *Diseases of the Nervous System*, reading in part:

When convulsive therapy is indicated * * * Indoklon * * * Eliminates patient fear and anxiety of electroshock, Indoklon pharmacconvulsive Therapy is safe and dependable * * *

failed to include a true statement of information relating to the side effects and contraindications of said drug as required by the regulations, 21 C.F.R. 1.105, since said advertisements failed to include any information relating to said side effects and contraindications.

4. By reason of the foregoing, the aforesaid article is held illegally within the jurisdiction of this Court, and is liable to seizure and condemnation pursuant to the provisions of said Act, 21 U.S.C. 334.

Wherefore, plaintiff prays that process in due form of law according to the course of this Court in cases of actions in rem issue against the aforesaid article; that all persons having any interest therein be cited to appear herein and answer the aforesaid premises; that this Court decree the condemnation of the aforesaid article and grant plaintiff the costs of this proceeding against the claimant of the aforesaid article; that the aforesaid article be disposed of as this Court may direct pursuant to the provisions of said Act; and that plaintiff have such other and further relief as the case may require.

Dated _____, 1967.

EDWARD V. HANRAHAN,
U.S. Attorney.

STATE OF ILLINOIS
County of Cook, ss:

AFFIDAVIT

Roger J. Balla, Assistant United States Attorney, being first duly sworn on oath, deposes and says that he has been appointed by Edward V. Hanrahan, United States Attorney for the Northern District of Illinois, to represent the United States of America in the instant cause; and that he has read the above complaint, and the complaint is true in substance and fact.

ROGER J. BALLA,
Assistant U.S. Attorney.

Subscribed and sworn to before me this _____ day of April, 1967.

Notary Public.

LAKESIDE LABORATORIES,
DIVISION OF COLGATE-PALMOLIVE CO.,
Milwaukee, Wis., November 1967.

DEAR DOCTOR: The Food and Drug Administration have requested that we call your attention to the monograph for Norpramin (desipramine hydrochloride) in the 1967 *PDR*: page 687, white section. The FDA consider this monograph incomplete (in relation to the official labeling, the package insert), and therefore potentially misleading as prescribing information to allow safe and effective use of the drug.

To provide you with the necessary adequate reference, we enclose a revised monograph for 1967 Physicians' Desk Reference in which the changes have been emphasized by italics. Please insert this revision opposite page 687.

Sincerely yours,

WILLIAM C. JANSSEN, M.D.

THE S. E. MASSENGILL Co.,
Bristol, Tenn., November 1, 1967.

DEAR DOCTOR: The Food and Drug Administration has requested that we call your attention to the monographs for our products, Predsem, Salcort and Salcort-Delta, in the current (1967) *Physicians' Desk Reference*. The FDA considers these monographs to be incomplete in presenting the necessary information for the safe and effective use of these drugs and ththerefore potentially misleading.