FEBRUARY 16, 1966.

Re *U.S.* v. *Wallace Laboratories*, criminal No. 322–65 DJ#FMV:JWD:ajw 21–48–334.

(Attention of Harold P. Shapiro, Chief, Administrative Regulations Section, Criminal Division.)

DEPARTMENT OF JUSTICE,
Washington, D.C.

SIRS: Reference is made to your letter dated February 9, 1966.

Please be advised that the Honorable Arthur S. Lane sentenced the above-named defendant to a fine of $1,000.00 on each of counts I and II of the information.

Respectfully,

DAVID M. SATZ, Jr.,
U.S. Attorney.

By MARK E. LITOWITZ,
Assistant U.S. Attorney.

In the United States District Court for the Northern District of Illinois Eastern Division

No. ———

(21 U.S.C. 331 and 333)

UNITED STATES OF AMERICA

v.

ABBOTT LABORATORIES, A CORPORATION

COUNT I

The United States Attorney charges:

That on or about May 6, 1965, Abbott Laboratories, a corporation, organized and existing under the laws of the State of Illinois and trading and doing business at North Chicago, Illinois, the defendant herein, did, within the Eastern Division of the Northern District of Illinois, 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 North Chicago, Illinois, for delivery to Milwaukee, Wisconsin, consigned to St. Mary's Hospital, a number of bottles containing a drug designated by the name "Eutonyl";

[2]

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

100 No. 6876 Filmtab EUTONYL 10 mg. PARGYLINE HYDROCHLORIDE

Caution. Federal (U.S.A.) law prohibits dispensing without prescription. Each tablet contains: Eutonyl (Pargyline Hydrochloride), N-Benzyl-N-methyl-2-propynylamine hydrochloride—10 mg. Lot No. 771–1413–22, Abbott Laboratories, North Chicago, Ill., U.S.A.

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)(i), substantially the same as the labeling authorized by the approved new drug application effective with respect to said drug.

[3]

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid was further misbranded within the mean-