ing of 21 U.S.C. 352(n) in that said defendant, the manufacturer of said drug, failed to include in the advertisement caused to be issued by said defendant with respect to said drug in the February 8, 1965 Edition of the Journal of the American Medical Association, a true statement of information in brief summary relating to the side effects, contraindications and effectiveness of said drug as required by regulations, 21 CFR 1.105(e) and (f), to wit, the aforesaid advertisement did not present a brief summary which fairly showed the effectiveness of said drug in the conditions for which it was recommended in the advertisement, together with a showing of all side effects and contraindications of said drug that were pertinent with respect to the uses recommended and suggested in said advertisement, including the information from the approved new drug application labeling for said drug concerning said side effects and contraindications.

United States Attorney for the
Northern District of Illinois.

In the United States District Court for the District of New Jersey

UNITED STATES OF AMERICA v. CIBA PHARMACEUTICAL COMPANY, DIVISION OF CIBA CORPORATION

Criminal No. 391–66 (21 U.S.C. 331(a) and 333(a))

Information

COUNT I

The United States Attorney charges:

That on or about September 30, 1964, CIBA Pharmaceutical Company, Division of CIBA Corporation, a corporation organized and existing under the laws of the State of Delaware, and trading and doing business at Summit, New Jersey, the defendant herein, did, within the District of New Jersey, 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 Summit, New Jersey, for delivery to Glendale, New York, consigned to Barry Division of Ketchum & Co., Inc., a number of bottles containing a drug, Esidrix-K.

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

Esidrix-K 50/1000. Each tablet contains Esidrix Brand of Hydrochlorothiazide 50 mg. Potassium Chloride 1000 mg. Caution: Federal law prohibits dispensing without prescription. Lot No. 282 305 CIBA Pharmaceutical Company, Summit, N.J.

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, a mailing piece identified as A/9507 February 1964 entitled in part "For 'K-Losers' in edema Esidrix-K," 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.

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C 352(n) in that said defendant the manufacturer of said drug, failed to include in the advertisement caused to be issued by said defendant with respect to said drug in the September 21, 1964 Edition of the Journal of the American Medical Association, a true statement of information in brief summary relating to the side effects, contraindications and effectiveness of said drug as required by regulations, 21 CFR 1.105(e) and (f), to wit, the aforesaid advertisement did not present a brief summary which fairly showed the effectiveness of said drug in the conditions for which it was recommended in the advertisement, together with a showing of all side effects and contraindications of said drug that were pertinent with respect to the uses recommended and suggested in said advertisement, including the information from the approved new drug application labeling for said drug concerning said side effects and contraindications.