COUNT II

The United States Attorney further charges:

That on or about November 13, 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 New York, New York, consigned to New York Division Ketchum & Co., Inc., a number of bottles containing a drug, Esidrix.

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

Esidrix Hydrochlorothiazide U.S.P. 25 mg. Each tablet contains Esidrix, brand of Hydrochlorothiazide USP 25 mg. Caution: Federal law prohibits dispensing without prescription. Lot No. 282281 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(a) 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.

COUNT III

The United States Attorney further charges:

That on or about April 8, 1965 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 New York, New York, consigned to New York Division of Ketchum & Co., Inc., a number of bottles containing a drug, Esidrix.

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

Esidrix Hydrochlorothiazide U.S.P. 50 mg. Each tablet contains Esidrix, brand of Hydrochlorothiazide USP 50 mg. Caution: Federal law prohibits dispensing without prescription. Lot No. 282 944 Ciba Pharmaceutical Company, Summit, N.J.

That said drug when caused to be introduced and delivered for introduction into interstate commerce as foresaid, 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 Physicians' 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.