tion 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 Cranbury, New Jersey, for delivery to Dallas, Texas, consigned to the Great Southwest Warehouses, Inc., a number of bottles containing a drug designated by the name "Pree MT";

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

"50 tablets Pree MT Each tablet contains meprobamate. . . . 200 mg. hydrochlorothiazide. . . . 25 mg. Caution: Federal law prohibits dispensing without prescription. Wallace Laboratories Division of Carter Products, Inc., Cranbury, N.J."

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was a drug required to be dispensed only upon prescription as provided by 21 U.S.C. 353(b)(1) since it was a drug intended for use by man and covered by an approved new drug application which became effective under 21 U.S.C. 355 prior to October 10, 1962, and which limited said drug to use under the professional supervision of a practitioner licensed by law to administer such drug;

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(n) in that said drug was a prescription drug distributed and offered for sale in the United States and said defendant, the manufacturer of said drug, failed to include in advertisements, caused to be issued by said defendant with respect to said drug in the editions of June 1, 1964, and June 8, 1964 of the Journal of the American Medical Association, a true statement of information in brief summary relating to the side effects and contraindications of said drug as required by Section 1.105(f)(2) of the regulations published in the Federal Register of January 10, 1964 (29 F.R. 257), to wit, the aforesaid advertisements did not present, from the labeling accepted in the aforesaid new drug application, as required by said regulations, information concerning certain side effects and contraindications of said drug that were pertinent with respect to the use recommended and suggested in said advertisements, namely, premenstrual tension, and with respect to the uses for which the dosage form advertised was commonly prescribed, namely, hypertension and congestive heart failure, since (1) the aforesaid advertisements did not state in brief summary or at all with respect to the side effects of said drug and its ingredients, namely hydrochlorothiazide and meprobamate, that excessive response and resulting undesirable electrolyte imbalance may be caused by the administration of said drug, that azotemia may be precipitated or increased by hydrochlorothiazide, that it may be necessary to discontinue administration of said drug to patients with severe liver or renal disease, that gout has been precipitated, that all patients on hydrochlorothiazide should be carefully followed to detect side reactions or unusual manifestations of drug idiosyncrasy, such as leukopenia, agranulocytosis, or aplastic anemia, that from the use of meprobamate allergic reactions most often in form of a skin rash, have been reported and, less frequently, more severe reactions (fever, angio-neurotic edema and bronchial spasm) have occurred, that other allergic effects from use of meprobamate though rarer, include nonthrombocytopenic purpura, chills, edema and arthralgia, and that said drug should be discontinued when hypersensitivity develops; and (2) the aforesaid advertisements contained the statement "Contraindications: None known" which was false and misleading as applied to said drug for which contraindications were known; and (3) the aforesaid advertisements did not state in brief summary or at all with respect to the contraindications of said drug and its ingredients, namely hydrochlorothiazide and meprobamate, that hydrochlorothiazide is contraindicated in the presence of anuria, that therapy with hydrochlorothiazide should not be reinstituted in patients who have had toxic reactions to hydrochlorothiazide, and that therapy with meprobamate should not be reinstituted in patients who have had an allergic reaction to meprobamate.

COUNT II (98–706 A)

The United States Attorney further charges:

That on or about June 26, 1964, Wallace Laboratories, Division of Carter Products, Inc., a Maryland Corporation, 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