from "A Scientific Exhibit Presented at The American College of Cardiology, Boston, Mass., February 17–21, 1965," offers the drug for the following purposes for which the drug is not generally recognized as safe and effective, and under the following representations of safety and efficacy, which purposes and representations are not contained in the labeling accepted by the Food and Drug Administration under the presently approved new drug application for the article:

(Package insert)—

1. "This drug increases blood flow and oxygen supply to the myocardium . . .
2. ". . . the dilation of the capillaries of the postarteriolar bed with a resultant greater flow of blood through the arteries and arterioles to supply these capillaries . . .
3. "This drug, because of its gradual onset of action, is safe for prolonged use in all patients with coronary artery disease, because it does not significantly change the blood pressure, cardiac output, or pulse rata . . .
4. ". . . for adequate, sustained increase in blood flow and oxygen supply to the myocardiam . . ."

(mailing piece identified "490T718 October, 1965")

1. that the drug is for use in the immediate postinfarction period and in acute coronary occlusion.
2. that a purportedly well-controlled clinical investigation, comparing patients treated with Peritrate SA with similar patients treated with a placebo beginning at a time closely following the onset of acute myocardial infarction, proved that the fact that 22 percent more patients treated with Peritrate SA remained alive after two years than patients treated with a placebo was due to the action of the drug.

4. That the aforesaid article was misbranded when introduced into and while in interstate commerce within the meaning of said Act, 21 U.S.C. as follows:

352(a) in that its labeling, namely, the mailing piece identified "498T718 October 1965," contains statements which represent and suggest that a purportedly well-controlled clinical investigation comparing patients treated with Peritrate SA with similar patients treated with a placebo beginning at a time closely following the onset of acute ayecardial infarction, proved that the fact that 22 percent more patients treated with Peritrate SA remained alive after two years than patients treated with a placebo was due to the action of the drug, which statements are false and misleading since they are contrary to fact; and in that said mailing piece also contains statements which represent and suggest that the referenced study by Lumb, G. D., and Hardy, L. B., Circulation (Pt. II, Cardiovascular Survery) 27:717, 1963, supports the claim in said mailing piece that "from the first sign and throughout the course of coronary artery disease . . . Peritrate SA (pentaerythritol tetranitrate) 80 mg. Sustained Action . . . stimulates development of collateral circulation," which statements are false and misleading since they are contrary to fact.

352(f)(1) in that its labeling fails to bear adequate directions for use and it is not exempt from such requirement, since it is a prescription drug within the meaning of 21 U.S.C. 353(b)(1)(C), and a new drug subject to the provisions of 21 U.S.C. 355, and its labeling, namely, the package insert, is not the labeling authorized in an approved new drug application as required under the exempting regulation 21 CFR 1.106(b)(3)(ii), and the mailing piece identified "4981718 October 1965," which is labeling within the meaning of (21 CFR 1.105(1)), is not substantially the same as the labeling authorized in an approved new drug application, as required under the exempting regulation 21 CFR 1.106(b)(4)(i).

352(n) in that it is a prescription drug distributed and offered for sale in the State of New York, and the advertisement for the drug appearing in the *Journal of the American Medical Association* from December 6, 1965 through January 3, 1966 and in the *Journal of the American Medical Association* for February 7, 1966, identified "PE–OP–527–4C December 1965," caused to be issued by the manufacturer, packer, or distributor of the drug, failed to include a true statement of information in brief summary relating to the effectiveness of said drug as required by regulations 21 CFR 1.105(e) in that the advertisement lacks fair balance in its presentation and does not fairly show the effectiveness of the drug in the conditions for which it is recommended or suggested in the advertisement since the advertisement represents (1) that a purportedly well-controlled clinical investigation, comparing patients treated with Peritrate SA with similar patients treated with a placebo beginning at a time closely following the onset of acute mycardial infarction, proved that the fact that 22