On August 3, 4 and 5, 1964, Food and Drug Administration Inspectors Carl E. Lorentzson and Charles Thorne inspected the firm and learned that it was still manufacturing the 30 milligram Obetrol tablet and capsule and shipping it in interstate commerce without an approved New Drug Application. As a follow-up to this inspection, the Food and Drug Administration collected samples of 30 milligram Obetrol time disintegration capsules and tablets in interstate commerce. (Counts I and II)

In the spring of 1964, the firm submitted a Supplemental New Drug Application. At that time, it came to the attention of the Bureau of Medicine of the Food and Drug Administration that the firm was advertising its 10 and 20 milligram Obetrol tablets with the use of false and misleading claims. Some of the objections raised by the Bureau of Medicine to the firm's advertising were as follows:

(1) It failed to list Obertol's side effects.

(2) It implied that Obetrol was unique in that it was safer and more effective than other amphetamines. This claim was unsupportable and illogical.

(3) It claimed that Obetrol was effective in "difficult cases," whereas, the two papers referred to in the advertisement did not demonstrate this fact. In addition, these two papers contained identical cases, were written by the same authors, but were published in two separate journals.

(4) It invited the misuse of the drug without proper regard for patient-safety by quoting, out of context, in such a way as to conceal the fact that some patients could not tolerate the drug at all, and others found it necessary to reduce the dosage to avoid dangerous side effects.

(5) It tampered with a direct quote through the insertion of a phrase, a wrongful act aggravated: (a) by the fact that there was no information in the author's article justifying the idea suggested in the inserted phrase; and (b) by the fact that the tampering invited a dangerous over-confidence in the use of Obetrol in cardiovascular patients in whom the drug was contraindicated.

The quote from the author's article reads as follows, with the words the defendants inserted being in brackets: "In the cooperative patient [Obetrol] was markedly beneficial in producing the desirable weight loss with minimal side effects, even in [the case of a high percentage of patients] with cardiovascular and other chronic ailments which [normally] make use of other amphetamines undesirable because of side effects."

On August 4, 1964, Mr. Armin Rosner and his attorney met with representatives of the Food and Drug Administration and were advised to discontinue their current advertising campaign with respect to Obetrol tablets. The firm then advised the representatives of the Food and Drug Administration that it manufactured and sold a 30 milligram Obetrol tablet and capsule without an approved New Drug Application, since it was of the opinion that the submission of a New Drug Application was not necessary, as it was selling this drug directly to physicians.

In a letter dated August 12, 1964, from Rexar Pharmacal Corporation to the Food and Drug Administration, the firm promised to discontinue all advertising of the Obetrol 10 and 20 mg. tablets and to discontinue the manufacture of Obetrol tablets and capsules in excess of 20 milligrams. The firm then proposed a revised labeling as part of its supplemental New Drug Application for Obetrol tablets. The final labeling for the drug was approved by the Food and Drug Administration on July 13, 1965.

Shortly after the labeling was approved, the Food and Drug Administration learned that the firm had once more reinstituted an advertising and promotional campaign for Obetrol. The firm placed an advertisement in the September 13, 1965, issue of *Modern Medicine*, which did not state in brief summary, or at all, those precautions as set forth in the approved New Drug Application labeling for the drug, which were pertinent with respect to the use recommended or suggested in the advertisement as required by the regulations 21 CFR 1.105(e) and (f)(2) in that the brief summary failed to state that the drug should be used with caution in individuals with anoxeria, insomnia, vasomotor instability, asthenia, psychopathic personality, a history of homicidal or suicidal tendencies, and individuals who are known to be hyperactive to sympathomimetic agents or emotionally unstable individuals who are known to be susceptible to drug abuse; and that certain monoamine oxidase inhibitors may potentiate the action of Obetrol. Consequently, the Food and Drug Administration collected a sample of Obetrol (Count V).

The defendants may claim that since the advertisement in *Modern Medicine* contained a brief summary of side effects and contraindications, as set forth