

capsules 3 or 4 times daily. Wyeth Laboratories, Inc. Philadelphia, Pa. * * *
Control No. 1660711 * * * (insert) "Serex (Oxerepam), Serex is 7-chloro-1,
3-dihydro-3-hydroxy-5-phenyl-23-1, 4-benzodiazepin-2-one. Wyeth Laboratories,
Inc. Philadelphia, Pa., Cir. 2473, January 24, 1966 * * *"

LIBEL OF INFORMATION

To The Honorable Judge of the United States District Court for the District of New Jersey.

Now comes the United States of America, by David N. Sats, United States Attorney for the District of New Jersey and shows to the Court:

1. That this libel is filed by the United States of America and prays seizure and condemnation of a certain article of drug, as hereinafter set forth, in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

2. That there is at Secaucus, New Jersey, in possession of Wyeth Laboratories, Division of American Drug Products Corporation, 555 Secaucus Road (warehouse), or elsewhere within the jurisdiction of this court, an article of drug consisting of 150 bottles, more or less labeled in part: (bottle) "100 Capsules 13737 Serea * * * 10 mg. Caution: Federal law prohibits * * * see accompanying information. Usual dosage: one or two capsules 3 or 4 times daily. Wyeth Laboratories, Inc., Philadelphia, Pa. * * *

3. That the aforesaid article was misbranded when introduced into and while in interstate commerce, within the meaning of said Act, 21 U.S.C. 352(a) in that it is a prescription drug within the meaning of 21 U.S.C. 353(b)(1)(C), it is distributed in the State of New Jersey, and the advertisement for the drug appearing in the April 25, 1956 issue of the *Journal of the American Medical Association*, in the March 1956 issue of *American Journal of Psychiatry*, and in the April 18, 1956 issue of *Medical Economics*, caused to be issued by the manufacturer, packer, or distributor of the drug lacks fair balance in its presentation and does not fairly show the effectiveness of the drug in the conditions for which it is recommended in the advertisement, as required by regulations 21 CFR 1.105(e), in that:

(A) The advertisement emphasizes use of Serex by elderly persons, and implies that Serex is quite safe for elderly persons through use of such statements as "Possesses extraordinary safety margin" and "stamia, drowsiness, dizziness rare," but fails to provide fair balance in that the advertisement does not emphasize the fact that Serex should be used cautiously in the elderly, particularly because of the possibility of serious hypotensive reactions in elderly persons.

(B) The advertisement refers to a study by Chesrow, et al., as one involving "145 elderly patients," but fails to show that the patient group of 145 ranged in ages from 33 to 97 (men) and 33 to 89 (women).

(C) The advertisement is false and misleading in that it quotes from the Chestos, et al paper a dosage of the drug up to 40 mg. a day; while the approved package labeling for ----- limits the initial dosage of the drug in "older patients" to 30 mg. a day; the advertisement thus misleadingly promotes a dangerous use in the age group on which the promotion is based.

(D) The advertisement promotes effectiveness of Serax by the claim "controls . . . anxiety-linked depression," which claim is not permitted in the approved package labeling; further, aluco "depression" may vary between neurosis and psychosis (Serax being contraindicated in psychotic patients), the claim is dangerous.

(E) The advertisement lacks "fair balance" since it selects one paper to emphasize favorable aspects of Serex therapy, in relation to a competitive product, while failing to mention other studies which present different views; and the advertisement falsely implies that the Chesrow et al paper represents the medical consensus as to the performance of Serex in comparison to chlorthalidopozide.

4. That by reason of the foregoing, the aforesaid article is held illegally within the jurisdiction of this Court, and is liable to seizure and condemnation pursuant to the provisions of said Act, 21 U.S.C. 354.

Wherefore, libellant prays that process is due form of law according to the course of this Court in cases of admiralty jurisdiction issue against the aforesaid article; that all persons having any interest therein be cited to appear herein and answer the aforesaid premises; that this Court decree the condemnation of the