and appear before the said Court, to be held in and for the Eastern District of New York on the 23rd day of March, 1966, at 10:30 a.m. of the same day, if the same shall be a day of jurisdiction, otherwise on the next day of jurisdiction thereafter, then and there to interpose a claim for the same, and to make their allegations in that behalf. And what you shall have done in the premises do you then and there make return thereof together with this writ.

Witness, the Honorable Joseph C. Zavatt Chief Judge of said Court, at the Borough of Brooklyn, in the Eastern District of New York, this the 28th day of February, in the year of our Lord one thousand nine hundred and sixty-six, and of the Independence of the United States of America the one hundred and ninetieth.

LEWIS ORGEL, *Clerk.*
By MARIE R. BARETTI,
Deputy Clerk.

In the United States District Court for the Eastern District District of New York

No. ——

UNITED STATES OF AMERICA

v.

An article of drug consisting of 63 bottles, more or less, of an article labeled in part: (btl.) "100 86 mg. Tablets Peritrate SA Sustained Action (Pentaerythritol tetranitrite) Caution: Federal law prohibits dispensing without prescription. Warner-Chilcott Laboratories Div., Morris Plains, N.J. Usual Adult Dose: b.i.d. 1 tablet immediately on arising and 1 tablet 12 hours later * * * Read accompanying directions * * * Quality Control No. 3264115B" (package insert) "3490243 Peritrate SA (pentaerythritol tetranitrate) Peritrate with Phenobarbital SA Sustained Action Each tablet contains: Phenobarbital 45 mg. (¾ gr.) * * * Pentaerythritol Tetranitrate 80 mg. * * *"

LIBEL OF INFORMATION

To The Honorable Judge of the United States District Court For The Eastern District of New York.

Now comes the United States of America, by Joseph P. Racy, United States Attorney for the Eastern District of New York 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 Glendale, New York, in possession of Barry Division of Ketchum and Company, Inc., 80–00 Cooper Avenue, an article of drug consisting of 63 bottles, more or less, of an article labeled in part: (btl.) "100 80 mg. Tablets Peritrate SA Sustained Action (Pentaerythritol tetranitrate) Caution: Federal law prohibits dispensing without prescription. Warner-Chilcott Laboratories Div., Morris Plains, N.J. Usual Adult Dose: b.i.d. 1 tablet immediately on arising and 1 tablet 12 hours later * * * Read accompanying directions * * * Quality Control No. 3264115B" (package insert) "3490243 Peritrate SA (pentaerythritol tetranitrate) Peritrate with Phenobarbital SA Sustained Action Each tablet contains: Phenobarbital 45 mg. (¾ gr.) * * * Pentaerythritol Tetranitrate 80 mg. * * *" which were shipped, on or about February 4, 1966, by Warner-Chilcott Laboratories, Inc., 201 Tabor Road, Morris Plains, New Jersey, via Parcel Delivery Service, Inc.

3. That the aforesaid article is a new drug which may not be introduced or delivered for introduction into interstate commerce, under said Act, 21 U.S.C. 355(a) since it is a new drug within the meaning of 21 U.S.C. 321(p) in that it is not generally recognized as safe and effective for the uses recommended or suggested in the labeling, and no approval of an application filed pursuant to 21 U.S.C. 355(b) is effective with respect to such drug for all of such uses, since the labeling of the drug, namely, the aforesaid package insert and the mailing piece which is identified "490T718 October, 1965," and contains the reprints entitled "Pentaerythritol Tetranitrate, As Adjunct Therapy In The Immediate Pastinfarction Period," reprinted from Angiology, Vol. 15, 11, November 1964, and "The Use Of Coronary Vasedilators In Acute Coronary Occlusion," reprinted