

NEA 6488

NOV 19 1948

Antra Pharmaceutical Products, Inc.
444 Madison Avenue
New York 22, New York

Gentlemen:

Attention of Mr. Erik Bisinger

This will acknowledge the receipt of reports of clinical trials on the use of "Xylocaine" as a local anesthetic in dentistry, dated November 12, 1948, submitted to us directly by Dr. J. P. Lazarsky, and also reports by Dr. J. L. Southworth and Dr. R. A. Ringen, sent to us by you. These have been considered as a part of your new drug application for Xylocaine.

We have completed our study of this application and in accordance with the provisions of the regulations under section 505(e) of the Act it has become effective.

Please submit five copies of the label and labeling when available.

We are requesting that as experience with this new anesthetic accumulates, you keep us informed by submission of copies of such work as may be published.

Very truly yours,

Erwin E. Nelson, M.D.
Acting Medical Director

Enclosure
Effective paragraphs

cc NY
cc Med Div
EEN/bb
11/18/48