Whereas the allowable upper limit of 5 mg. Coumadin Tablets is 5.25 mg., the above lots range from 5.49 mg, to 5.56 mg. per tablet.

Only the above packaging lots are involved.

Please return *only these lots* of Coumadin immediately as follows:

1. Fill out and *enclose* the packing slip with the merchandise.
2. Use the enclosed postage paid address label on the package. No stamps required. Do not insure.

We will immediately replace the merchandise returned.

This recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your assistance.

Sincerely yours,

ENDO LABORATORIES INC.

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ASTRA PHARMACEUTICAL PRODUCTS, INC.,
*Worcester, Mass., August 23, 1967.*

DEAR DOCTOR: The Food and Drug Administration has asked us to call to your attention two of our recent mailing pieces for Citanest® which the FDA regards as so substantially misleading and lacking in adequate professional use information that in its view they represent potential hazards to health. These mailing pieces, identified as 118–67 and 119–67, should be discarded if still in your possession.

*1. Intravenous Regional Anesthesia*

Mailing piece 118–67 recommended the use of Citanest in intravenous regional anesthesia. The FDA regards use of this drug by that technique as experimental. The package insert for Citanest contains no information for its use in intravenous regional anesthesia and the drug has not been approved for used in that procedure.

*2. Maximum Single Dosage*

Mailing pieces 118–67 and 119–67 contained statements which implied that dosages of Citanest in excess of the maximum single dose (600 mg.) could be employed in clinical use. No such implication was intended by Astra, and Astra reaffirms that no more than 600 mg. of the drug should be used during any two-hour period.

*3. Professional Use Information*

Both booklets omitted essential and required professional use information. The attached page contains the warning, precautionary, and adverse reaction information which was omitted from the "full disclosure" sections of the booklets.

The safety and effectiveness of Citanest (prilocaine), when used in accordance with the conditions specified in the enclosed package insert, are not in question.

Sincerely yours,

ASTRA PHARMACEUTICAL PRODUCTS, INC.

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NEISLER LABORATORIES, INC.,
SUBSIDIARY OF UNION CARBIDE CORP.,
*New York, N.Y., August 11, 1967.*

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to a recent advertisement for Diutensen-R which the FDA regards as misleading.

The Food and Drug Administration regards the warning information in the ad to be so substantially deficient that the ad represents a potential danger to health. Therefore, we have rewritten our "Brief Summary", and the nature and extent of the changes are shown in capital letters in the attached revision. We have discontinued the ad in question and all future ads will carry the new "Brief Summary".

The safety and efficacy of Diutensen-R are not in question when used in accordance with the prescribing information in the official package insert.

Sincerely,

NEISLER LABORATORIES.