to your attention the fact that the package inserts of the products listed below are being revised to contain the following prominently displayed warning:

Warning: Fatalities have occurred due to the development of Stevens-Johnson syndrome (erythema multiforme exudativum) following the use of (drugs listed below). Therefore, the patient must be closely observed and should a rash develop during therapy with (drugs listed below), the drug should be discontinued immediately.

(Drugs listed below) is a sulfonamide which maintains a long-lasting blood level due to slow excretion. Because of the long-lasting blood levels, a smaller dosage than is normally employed with shorter-acting sulfonamides should be administered. Since the short-acting sulfonamides are effective for most of the same conditions, their use should be considered before the long-acting sulfonamides are employed.

Serious reactions associated with the use of long-acting sulfonamides should be reported promptly to the manufacturer or to the Food and Drug Administration.

Lederle Laboratories Division

KYNEX® (sulfamethoxypyridazine) Tablets.
KYNEX® ACETYL (n' acetyl sulfamethoxypyridazine) Pediatric Suspension.
AZO KYNEX® (phenylazodiamino-pyridine HCI sulfamethoxypyridazine) Tablets.

Parke, Davis & Co.

MIDICEL® (sulfamethoxypyridazine) Tablets.
MIDICEL® ACETYL SUSPENSION (n' acetylsulfamethoxypyridazine).

Roche Laboratories

MADRIBON® (sulfadimethoxine), Tablets, Chewable Tablets, Suspension, Pediatric Drops.

MADRICIDIN® Capsules: Each capsule contains: sulfadimethoxine, phenindamine tartrate, acetaminophen, caffeine.

ROCHE LABORATORIES,
DIVISION OF HOFFMANN-LA ROCHE, INC.,
Nutley, N.J., December 30, 1965.

IMPORTANT: DRUG RECALL

DEAR DOCTOR: Hoffmann-La Roche, has agreed at the request of the Food and Drug Administration, to suspend sales of Librax® Capsules and withdraw all existing stocks from the market. In view of the widespread use of this product since 1961, we feel that an explanation of the circumstances leading to this withdrawal is in order.

In November, we advised you that we had received isolated reports of enhanced atropine?like side effects in patients on Librax therapy and had determined by the use of new analytical procedures that certain specific batches of Librax contained a trace amount of an analog of the clidinium bromide component which accounted for these effects. At that time, we voluntarily withdrew the involved lots and replaced pharmacists' stocks with capsules which had passed our new analytical procedure. Up to this time we have received no reports of adverse reactions involving this new material.

Because all Librax stock is being withdrawn, your patients will not be able to refill their present supplies once they have been exhausted.

As you know, all new drugs must be the subject of an approved New Drug Application in order to be marketed. We have been advised by the Food and Drug Administration that it was not willing to approve a supplement we had filed to our New Drug Application on Librax, concerning the clidinium bromide component. This supplement contained revised analytical procedures, data on the supplier of clidinium bromide and other technical information. The Librax on the market was produced in accordance with these revisions. As a result, on December 28th the Food and Drug Administration requested us to withdraw all supplies of Librax or the necessary legal steps would be initiated to have it removed since the Librax currently on the market was not produced in accord-