

List No.	Product description	Control No.
84221	Streptomycin sulfate injection 0.5 gm/cc. 2 cc. vial.....	{5M811 6C672 5M908
84231	Streptomycin sulfate injection 0.5 gm/cc. 10 cc. vial.....	{5M835 6D999
84826	Streptomycin sulfate injection 0.4 gm/cc. 2.5 cc. vial.....	5W748

These control numbers are the only ones involved.

The above action has been discussed with and agreed to by the scientific staff of the Food and Drug Administration.

We sincerely regret this incident and request your cooperation by promptly returning the material.

NEISLER UNION CARBIDE,
June 7, 1966.

DEAR DOCTOR: This is a drug recall notice.

Please immediately stop using all stocks of *Unitensen Aqueous*. Return to us by insured parcel post your complete inventory of *Unitensen Aqueous*. Do not include any other merchandise with this shipment.

Neisler Laboratories, Inc. will issue full credit to you and also reimburse you for the parcel post expenses.

This recall notice is being sent you because our current laboratory tests indicate that the potency of some batches of *Unitensen Aqueous* may sometimes diminish during storage under some conditions. Pending further work we are recalling this product. The Food and Drug Administration has been advised of our action.

We have *not* received any reports indicating a lack of safety or efficacy for *Unitensen Aqueous*. Our decision to withdraw the product is solely based on the fact that it appears to have inadequate shelf stability.

Sincerely,

GERAAD G. HUNT,
Executive Vice President.

CHAS. PFIZER & Co., INC.,
New York, N.Y., May 18, 1966.

Re Buclizine-containing drugs.

DEAR DOCTOR: The Food and Drug Administration has requested that the package inserts for buclizine-containing products be revised to contain the following statement:

"Contraindication: Buclizine, when administered to the pregnant rat, induced fetal abnormalities at doses above the human therapeutic range. Clinical data are not adequate to establish nonteratogenicity in early pregnancy. Until such data are available, buclizine is contraindicated for use in early pregnancy."

Buclizine is contained in Pfizer Laboratories' Terracydin Capsules, and in J. B. Roerig's Tetracydin Capsules and Tao AC Capsules.

We have obtained F.D.A. approval to remove buclizine from each of these products in order to eliminate this contraindication to use in pregnancy. All new production of these products will omit buclizine from the formulations.

However, we have on hand a sizable inventory of each of these drugs containing buclizine not yet finally packaged and which will not be exhausted for several months. This inventory will contain a package insert which includes the contraindication quoted above.

Sincerely yours,

J. RALPH FOWLER, M.D.,
Medical Director,
J. B. Roerig & Co.
JOHN L. WATTERS, M.D.,
Medical Director,
Pfizer Laboratories.