ple folders are all dated *8/10/65*, which is shown on the outside of the folder.

Because of this incorrect quantitative statement of hydrochlorothiazide, it is respectfully requested that you destroy these two sample folders that are in your possession. At the same time, we ask that you sign and return the enclosed postpaid card for our records.

The two sample folders of BUTISERPAZIDE–50 were mailed in a small box together with two similar folding catch-cover sample folders of BUTISERPAZIDE–25, which are correct in every respect and need not be destroyed.

We regret any inconvenience caused you, and will appreciate your prompt attention to this matter.

R. R. SMITH, M.D.,
Medical Director.

PFIZER LABORATORIES,
New York, N.Y., 19, 1965.

DEAR DOCTOR: Subsequent to the market introduction of Tyzine® (tetrahydrozoline HCl) in 1954, infrequent instances of drowsiness have occurred when the drug has been administered to children under two years of age. Marked somnolence or even shock, especially after ingestion of the solution, has been encountered rarely. In every instance the effect has been reversible and without sequelae. A caution regarding the possible occurrence of this syndrome in cases of overdosage has appeared in the Tyzine package circular. Nevertheless, infrequent instance of this effect in children under two have continued to be reported.

Therefore, in consultation with the Food & Drug Administration the Tyzine labelling has been revised to contraindicate its use in children under two years of age.

Tyzine has been successfully employed as a topical nasal decongestant throughout the country for the last 10 years. It continues to be a most valuable therapeutic agent for the relief of inflammatory hyperemia and edema of the nasal mucosa and congestive obstruction of sinus and Eustachian ostia, as may occur in the common cold, hay fever, and other related disorders, in patients over two years of age. Tyzine 0.1% (Spray or Drops) may be used in patients over 6 years of age. Tyzine Pediatria .05% (Drops) should be used in patients from 2 to 6 years of age. For complete dosage and prescription information, please consult the accompanying package circular.

Sincerely,

JOHN L. WATERS, M.D.,
Medical Director, Pfizer Laboratories.

MARCH 1, 1965.

To: All Physicians
From: CIBA Pharmaceutical Company, Division of CIBA Corporation; Merck Sharp & Dohme, Division of Merck & Co., Inc.

We should like to call your attention to the attached reprint entitled "Ulcerative-Obstructive Lesions of the Small Intestine," which appeared in the J.A.M.A. *191*:116–119, Feb. 22, 1965. This article contains the most comprehensive information on this subject to date. You will also be interested in an editorial concerning this subject in the same issue of the Journal.

The available information based on the results of the hospital survey and other reports has implicated coated potassium salts in about half the known patients who have developed the obstructive-ulcerative lesion. Therefore, coated potassium-containing formulations should be administered only when indicated and when adequate dietary supplementation is not practical. Such preparations should be discontinued if abdominal pain, distention, nausea, vomiting or gastrointestinal bleeding occurs.

As a result of these findings, Merck Sharp & Dohme, CIBA and the FDA concluded that an informative statement be incorporated in the labeling of appropriate products. Subsequently the FDA has requested *all* manufacturers of thiazide and certain other oral diuretics as well as coated potassium salt preparations to add the following statement to the labeling of all such products:

Warning:

There have been several reports, published and unpublished, concerning nonspecific small bowel lesions consisting of stenosis with or without ulceration associated with the administration of enteric-coated thiazides with potassium