

packaged and labeled internally by us, so in the interest of expediency we are asking you to destroy all Pfizer Laboratories and J. B. Roerig samples.

As to trade packages of Pfizer Laboratories and J. B. Roerig drugs, you can have every confidence that when the pharmacist fills your prescriptions for these products they will continue to meet every applicable standard of identity, quality, purity and labeling.

Needless to say, we regret this situation and any inconvenience it causes you and we assure you that every step is being taken to prevent its recurrence. We will expend every effort to replenish your supply of Pfizer drug samples as rapidly as possible but if at any time you are faced with a need for samples, in the interim, may we suggest that you contact your Pfizer Laboratories or J. B. Roerig professional service representative.

Sincerely yours,

J. PHILIP SMITH,
Group Vice President.

MERCK SHARP & DOHME RESEARCH LABORATORIES,
DIVISION OF MERCK & Co., INC.,
West Point, Pa., April 13, 1966.

Subject: Association of positive Coombs test with Aldomet® therapy.

I should like to call your attention to a recent addition we have made in the enclosed package circular for our product Aldomet (methyldopa). You will find the new reference encircled in the Side Effects section of the circular. The same change will be made in the Aldoril® package circular.

As background, there has been a recent report in the British literature by Carstairs, Worledge, Dollery and Breckenridge. They noted two patients in whom hemolytic anemia with a direct positive Coombs test developed after more than one year of treatment with Aldomet. They have reported also observations of a positive antiglobulin (Coombs) reaction in six patients receiving Aldomet in whom there was no evidence of hemolysis, reticulocytosis, or anemia. A copy of their paper is attached.

Further observations during the past few weeks both in England and the United States have confirmed the fact that some patients receiving Aldomet may develop a positive direct Coombs test without demonstrating any evidence of anemia, reticulocytosis or hemolysis. Several studies are now under way to determine the mechanism of these reactions, and whether they are the result of an altered immunologic process or a chemical interference with the Coombs reaction by Aldomet or any of its metabolites.

These observations suggest that if unexplained direct positive Coombs reactions are found in the course of crossmatching studies for transfusions, the possibility should be taken into account that Aldomet is being administered to such patients and might elicit such reactions.

If you have noted this occurrence in your own experience, I would appreciate learning of your observations.

Sincerely yours,

ELMER ALPERT, M.D.

PFIZER LABORATORIES,
DIVISION OF CHAS. PFIZER & Co., INC.,
New York, N.Y., April 1, 1966.

IMPORTANT SAMPLE RECALL

DEAR DOCTOR: In reviewing our inventory of physician samples, we have found a small number of 100 mg. Dibinese (chlorpropamide) tablet samples, lot 46460, incorrectly identified by the card enclosed with them as 250 mg. Diabinese tablets. Because the possibility exists that this incorrect card may have been employed in other samples in lot 46460, we are recalling this entire lot of 100 mg. samples. No other lots are involved, nor are any 250 mg. sample tablets involved.

The sample in question is a unit consisting of a seven-tablet circular plastic dispenser, a large printed card with a brochure in its pocket, and a booklet entitled "If You Have Diabetes," all enclosed in a clear acetate wrapper. Please inspect your total inventory of Diabinese samples of this type. If you have any, remove the booklet and the card containing the brochure. The lot number is em-