ance with the provisions of the original New Drug Application. Under these circumstances we elected to withdraw the stocks of Librax.

Since clinical experience has shown that Librax can be a valuable therapeutic aid for many patients, and we continue to be convinced that Librax is a safe and effective drug, we shall continue to explore with the Food and Drug Administration means for marketing Librax again as soon as possible. Meanwhile, we regret any inconvenience this may cause you and your patients and pledge our continuing efforts to make available drugs assuring patient benefits in efficacy, safety and practicality.

Sincerely,

ROBERT E. DIXON, M.D.,
*Director, Professional Services.*

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ROCHE LABORATORIES,
*Nutley, N.J., November 19, 1965.*

DEAR DOCTOR: Over the last two weeks we have received isolated reports from widely scattered communities to the effect that a few patients were experiencing enhanced atropine-like side effects in response to Librax therapy, such as blurring of vision, dryness of mouth, urinary hesitancy and constipation.

Assays of the clidinium bromide component of certain of the offending capsules indicated their conformance to the normal rigid quality control standards. Not content with these assays we submitted the capsules to a more critical test—a newly developed thin-layer chromatographic procedure that is far more sensitive than the method heretofore employed. This new procedure will be used in all future assays of the anticholinergic agent in Librax.

The presence of a trace amount of an analog of clidinium bromide at approximately the level of one two-millionths of an ounce per capsule was revealed in certain recently distributed batches of Librax—infinitesimal but sufficient to account for the enhanced atropine-like effects reported.

Therefore, we are voluntarily replacing all involved lots of Librax presently in distribution. Librax is the only Roche product containing clidinium bromide. Your pharmacist will have new stocks within ten days.

Physicians should be alert to the possibility of increased reports of these atropine-like side effects in patients receiving Librax, particularly the elderly and those receiving higher dosages. Therapy should be discontinued in patients who exhibit these symptoms until they can purchase new supplies.

Any Librax samples or trade packages with lot numbers beginning 143—through lot numbers beginning 172—which you presently have on hand should be destroyed. You will receive fresh clinical supplies from your Roche representative or through the mail within the next three weeks by sending the enclosed business reply card.

We want you to know that you can continue to prescribe Librax with confidence based not only on your clinical experience with the drug but also on this further proof of Roche's continuing effort to improve and sustain precise quality control.

A Librax package circular is enclosed for your reference.

Sincerely,

ROBERT E. DIXON, M.D.,
*Director, Professional Services.*

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MCNEIL LABORATORIES, INC.,
*Fort Washington, Pa., November 12, 1965.*

IMPORTANT: SAMPLE LABEL PRINTING ERROR BUTISERPAZIDE®–50, BATCH 8948, DATED 8/10/65

DEAR DOCTOR: During the period October 13 to October 15, 1965, you may have received two folding catch-cover samples of tablets BUTISERPAZIDE–50, which we mailed to physicians in your area. Each such sample folder was labeled correctly on the outside and inside "BUTISERPAZIDE®–50" and contained four, orange BUTISERPAZIDE–50 tablets in transparent film jackets. However, due to incorrect printing, as you will note on the facsimile provided below, the quantitative formula information lists the hydrochlorothiazide content in each tablet as 25 milligrams (⅜ grain) when in fact they contain 50 milligrams (¾ grain); also, immedidately below the formula information, it is stated the tablets are "Colored Green" when in fact they are colored orange. These incorrect sam-