treatment of hypertension where the development of mild hypokalemia might have serious consequences.

The following preparations will be affected by these required labeling changes:

Merck Sharp & Dohme

HydroDIURIL-Ka (hydrochlorothiazide with potossium chloride); Hydropres-Ka (hydrochlorothiazide reserpine, potassium chloride).

Eli Lilly & Co.

Anhydron K (cyclothiazide with potassium chloride); Anhydron KR (cyclothiazide with potassium chloride and reserpine).

E. R. Squibb & Sons

Naturetin c K (bendroflumethiazide with potassium chloride); Rautrax (rauwolfia serpentina whole root, flumethiazide potassium chloride); Rautrax-N Modified (rauwolfia serpentina whole root, bendroflumethiazide with potassium chloride); Rautrax-N (rauwolfia serpentina whole root, bendroflumethiazide with potassium chloride).

Ciba Pharmaceutical Co.

Esidrix-K (hydrochlorothiazide and potassium chloride).

It should be noted that the labeling for all capsules or tablets which provide 100 mg. or more of potassium per dosage unit or in the case of liquid preparations 20 mg. of potassium per milliliter are required to contain the warning concerning the occurrence of ulcerative-stenotic bowel lesions or directions for dissolving or diluting the preparation adequately to minimize the possibility of gastrointestinal injury. Potassium preparations with this potential hazard should be used only when adequate dietary supplementation is not practical.

To assist us in further evaluation of this problem, the Food and Drug Administration would appreciate your reporting to us any cases of the small bowel lesion associated with the use of thiazide and potassium preparations either alone or in combination.

Your cooperation will be greatly appreciated.

Sincerely yours,

HERBERT L. LEY, Jr., M.D.,
Director, Bureau of Medicine.

ROCHE LABORATORIES,
DIVISION OF HOFFMANN-LA ROCHE, INC.,
Nutley, N.J., March 10, 1967.

DEAR DOCTOR: At the request of the Food and Drug Administration, we are extending the "brief summary" of prescribing information for Librium® (chlordiazepoxide HCl) which appears in medical journal advertisements by adding several phrases and items from the unchanged official package circular.

The revised "brief summary" for medical journals is attached, indicating by capitalization the requested added material. Prescribing information in all Librium (chlordiazepoxide HCl) package circulars, direct mail information and brochures is complete and requires *no* change. The safety and effectiveness of the product are *not in question.*

In addition, in future medical journal advertisements for Librium (chlordiazepoxide HCl) in geriatric patients, we are amplifying statements which have appeared concerning possible side effects and initial dosage:

The statement that "Side effects in most instances are mild in degree and readily reversible with reduction of dosage," will be extended by the observations made in our package circular which point out that drowsiness, ataxia and confusion have been reported in some patients, particularly the elderly and debilitated, occasionally at lower dosage ranges, and that in a few instances syncope has been reported.

Whereas in geriatrics, the *usual daily dosage* is 5 mg, two to four times daily, the *initial dosage* in elderly and debilitated patients should be limited to 10 mg or less per day, adjusting as needed and tolerated.

We hope the additional detail in medical journal advertising clarifies the use of the product in accordance with the enclosed package circular.

Sincerely,

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