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.

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR LIBRIUM®
(CHLORDIAZEPOXIDE HCL)

(NOTE.—This revised "brief summary" for use in future medical journal advertising contains additional phrases and items (printed in capital letters) from the official package circular which remains unchanged.)

Before prescribing, please consult complete product information, a summary of which follows:

Contraindications.—Patients with known hypersensitivity to the drug.

Warnings.—Caution patients about possible combined effects with alcohol and other CNS depressants. AS WITH ALL CNS-ACTING DRUGS, CAUTION PATIENTS against hazardous occupations requiring complete mental alertness (*E.G.*, OPERATING MACHINERY, DRIVING). THOUGH PHYSICAL AND PSYCHOLOGICAL DEPENDENCE HAVE RARELY BEEN REPORTED ON RECOMMENDED DOSES, use caution in administering to addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in pregnancy, lactation, or in women of childbearing age requires that its potential benefits be weighed against its possible hazards.

Precautions.—In the elderly and debilitated, and in children over SIX, limit to smallest effective dosage (INITIALLY 10 MG OR LESS PER DAY) TO PRECLUDE ATAXIA OR OVERSEDATION, increasing gradually as needed and tolated. NOT RECOMMENDED IN CHILDREN UNDER SIX. THOUGH GENERALLY NOT RECOMMENDED, IF COMBINATION THERAPY WITH OTHER PSYCHOTROPICS SEEMS INDICATED, CAREFULLY CONSIDER INDIVIDUAL PHARMACOLOGIC EFFECTS, PARTICULARLY IN USE OF POTENTIATING DRUGS SUCH AS MAO INHIBITORS AND PHENOTRIAZINES. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (*E.G.*, EXCITEMENT, STIMULATION AND ACUTE RAGE) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies MAY BE PRESENT AND PROTECTIVE MEASURES NECESSARY. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established clinically.

Adverse reactions.—Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. IN A FEW INSTANCES syncope HAS BEEN REPORTED. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reductions; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction HAVE BEEN REPORTED occasionally, making periodic blood counts and liver-function tests advisable during protracted therapy.

Usual daily dosage.—Individualize for maximum beneficial effects. *Oral*—Adults: Mild and moderate anxiety and tension, 5 or 10 mg t.i.d. or q.i.d.; severe states, 20 or 25 mg t.i.d. or q.i.d. Geriatric patients: 5 mg b.i.d. to q.i.d. (SEE PRECAUTIONS.)

Supplied.—Capsules, 5 mg, 10 mg and 25 mg—bottles of 50.

ORTHO PHARMACEUTICAL CORP.,
Raritan, N.J., February 1, 1967.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to the fact that a claim in our recent advertising of ORTHO-NOVUM SQ* may be misleading.

In our introduction of this product to the medical profession we featured the