THIAZIDE REACTIONS INCLUDE: ANOREXIA, NAUSEA, VOMITING, DIARRHEA, headache, skin rash, dizziness, paresthesia, weakness, photosensitivity, jaundice, and pancreatitis. Reported rauwolfia reactions include: nasal stuffiness, nausea, weight gain, diarrhea, aggravation of peptic ulcer, epistaxis, skin eruption, AND REDUCTION OF LIBIDO AND POTENCY EXCESSIVE DROWSINESS, FATIGUE, WEAKNESS, AND NIGHTMARES MAY SIGNAL EARLY SIGNS OF MENTAL DEPRESSION.

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WALLACE PHARMACEUTICALS,
DIVISION OF CARTER-WALLACE, INC.,
*Cranbury, N.J.*

DEAR DOCTOR: At the request of the Food and Drug Administration, we are calling your attention to one of our recent advertisements captioned, "*The published clinical studies indicate: 3 of 4 non-psychotic depressions respond to 'Deprol.'*" The FDA considers that this advertising may have been misleading.

In the advertisement, we listed 21 studies comprising the total published 'Deprol' literature containing data on *non-psychotic* depressions. While the ad does not reflect the fact, data from these studies were *excluded* in whole or in part if—

(*a*) the diagnosis was not entirely clear;

(*b*) the recommended maximum dose of 6 'Deprol' tablets per day was exceeded;

(*c*) other psychotropic drugs or electroshock were part of therapy.

Moderate, marked, excellent, and complete responses were counted as favorable, while mild, fair, slight, and no responses were counted as unfavorable.

Using the above criteria, the final number of patients included was 323 selected from ten of the 21 listed studies. Nine of the ten studies were uncontrolled, and most patients in the ten studies concomitantly received informal or structured psychotherapy. The reported therapeutic results (ranging from 0% in a study with two non-psychotic depressed patients, through 64% in a study with 53 such patients, to 90% in two studies with 38 and 41 such patients respectively) also include, to an undetermined degree, placebo responses and spontaneous remissions known to occur in the therapy of neurotic depression.

The factors noted above represent problems that exist in working with any literature and are present in some 'Miltown' advertisements carrying the theme "one of a series." In order to avoid any misunderstanding, we have discontinued the use of these 'Miltown' advertisements as well as the described 'Deprol' advertisement.

Sincerely,

WALLACE PHARMACEUTICALS.

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ROCHE LABORATORIES,
DIVISION OF HOFFMANN-LA ROCHE, INC.,
*Nutley, N.J.*

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.