ARDSLEY, N.Y.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to recent journal advertisements for our products (Hygroton® and Regroton®) which the FDA considers to be misleading.

Hygroton Advertisement

This ad is headlined, "Do your patients shell out too much for a diuretic?". It states that a published report on a new short-acting diuretic supports the claim that "If one considers maximum recommended doses for each product, tablet for tablet Hygroton was clearly superior. Two tablets of Hygroton were found to produce almost 40% more natruresis and 20% more weight loss than five tablets of the other diuretic."

The FDA points out that the studies were based on small numbers of patients (6 to 13), that the actual differences reported were clinically insignificant, and that the ad's claim for superiority was not supported by the data or by the authors' conclusions. Further, the report was not a direct comparative study of the two drugs, but rather a comparison of data obtained on the new diuretic with data obtained on Hygroton in a previous study.

In addition, the tablet-for-tablet comparison in the ad is not regarded as sound because single tablets of Hygroton and the other diuretic do not contain comparable therapeutic dosages.

Regroton Advertisement

This ad displays a single Regroton tablet in relation to two sets of five tablets representing drug regimens for treating hypertension. The ad states that "in moderate hypertension" Regroton was "better than reserpine + hydralazine + hydrocholorothiazide in 41 of 43 patients and better than reserpine + methyldopa + hydrochlorothiazide in 34 of 37 patients". These numbers, taken from a paper referenced in the ad, refer specifically to a comparison of average mean blood pressures after two years on Regroton with responses to prior therapy utilizing the other drug combinations.

The FDA points out that the differences observed in the blood pressure response to the various treatments were neither statistically nor clinically significant. Further, the study was not done on patients diagnosed as "moderate hypertension", and the authors did not state that the effect of Regroton on the patients' blood pressure was "better".

The FDA also considers the summary of prescribing information in each ad to be inadequate. Each enclosed "Brief Summary" contains information in capital letters that was not included in our current ads. We are discontinuing the ads in question and future advertising will incorporate the revised "Brief Summary". The safety and effectiveness of the products are not in question when used in accordance with the official package inserts.

GEIGY PHARMACEUTICALS.

(NOTE.—This revised "Brief Summary", for use in future medical journal advertising, contains additional words and phrases (printed in capital letters) taken from the official package insert.)

BRIEF SUMMARY OF HYGROTON®—BRAND OF CHLORTHALIDONE

Indications: Hypertension and many types of edema involving retention of salt and water.

Contraindications: Hypersensitivity and most cases of severe renal of hepatic disease.

Warning: With the administration of enteric-coated potassium supplements, WHICH SHOULD BE USED ONLY WHEN ADEQUATE DIETARY SUPPLEMENTATION IS NOT PRACTICAL; the possibility of small bowel lesions (OBSTRUCTION, HEMORRHAGE, AND PERFORATION) should be kept in mind. SURGERY FOR THESE LESIONS HAS FREQUENTLY BEEN REQUIRED AND DEATHS HAVE OCCURRED. DISCONTINUE ENTERIC-COATED POTASSIUM SUPPLEMENTS IMMEDIATELY IF OBDOMINAL PAIN, DISTENTION, NAUSEA, VOMITING, OR GASTROINTESTINAL BLEEDING OCCUR.

Use with caution in pregnant patients, since the drug may cross the placental barrier and adverse reactions which may occur in the adult (thrombocytopenia, hyperbilirubinemia, altered carbohydrate metabolism, etc.) are potential problems in the newborn.