perglycemia, hyperuricemia, lassitude, restlessness, transient myopia, impotence or dysuria, orthostatic hypotension which may be potentiated when chlorthalidone is combined with alcohol, barbiturates or narcotics, leukopenia, aplastic anemia, skin rashes, THROMBOCYTOPENIA, AGRANULOCYTOSIS, nasal stuffiness, increased gastric secretions, nightmare, purpria, urticaria, ecchymosis, weakness, uvetis, optic atrophy and glaucoma, and PRURITUS. ERUPTIONS AND/OR FLUSHING OF THE SKIN, A REVERSIBLE PARALYSIS AGITANS-LIKE SYNDROME, INCREASED SUSCEPTIBILITY TO COLDS, DYSPNEA, weight gain, decreased libido, DRYNESS OF THE MOUTH, deafness, ANOREXIA, AND PANCREATITIS WHEN EPIGASTRIC PAIN OR UNEXPLAINED G.I. SYMPTOMS DEVELOP AFTER PROLONGED ADMINISTRATION. Jaundice, xanthopsia, PARESTHESIA, PHOTOSENSITIZATION and necrotizing angiitis ARE POSSIBLE.

Average dosage.—One tablet daily with breakfast.

Availability.—Pink, single-scored tablets in bottles of 100 and 1000.

PFIZER LABORATORIES,
DIVISION, CHAS. PFIZER & CO., INC.,
New York, N.Y., May 22, 1967.

DEAR DOCTOR: The Food and Drug Administration has requested that we call your attention to recent promotional messages for our products (Rondomycin, Renese, and Renese-R) which the FDA regards as potentially misleading.

RENESE AND RENESE-R

The monograph in the 1967 *Physicians' Desk Reference* for Renese and Renese-R is considered inadequate in presenting information necessary for their safe and effective use. To provide you with the necessary additional information, we are enclosing a revised monograph for insertion into your *PDR*. The changes include additional warnings and precautions concerned with electrolyte imbalance, hepatic coma, maintenance dosage, and, in the case of Renese-R, the possibility of Parkinsonism and confusion.

RONDOMYCIN

The FDA has also asked us to call to your attention certain features of our current advertising for the broad spectrum antibiotic, Rondomycin. The ad does not disclose that it is a member of the bacteriostatic tetracycline family and that administration for ten days is especially important in the treatment of Beta-hemolytic streptococcal infections. In referring to the "Protective dose (PD_{50}) tests," the ad did not specify that they were performed in mice utilizing laboratory strains of organisms injected intraperitoneally. While demonstrating the activity of Rondomycin against these test strains, the PD_{50} tests cannot be extrapolated directly to the clinical situation, in which sensitivity testing is recognized to be important for selection of the most appropriate antibiotic for a specific patient's infection.

In addition, the "Brief Summary" of warning information in the above ad, and also in the current journal ad for Renese-R, is considered inadequate. We are modifying the advertisements in question and future advertising will include the requested additional warning information.

Sincerely yours,

JOHN L. WATTERS, M.D.,
Medical Director.

ABBOTT LABORATORIES,
North Chicago, Ill., April 13, 1967.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to a recent advertisement on Enduron® (methyclothiazide) and Enduronyl® (methyclothiazide and deserpidine). The advertisement, headlined "Thiazide-potassium problems, doctor?" is regarded by the FDA as misleading.

The ad states that the advertised drugs provide "excellent sodium output with less potassium loss than either chlorothiazide or hydrochlorothiazide."

The consensus of expert medical opinion is that there is no significant difference in the amount of potassium loss caused by thiazide agents, including methyclothiazide (Enduron).