To provide you with the necessary information, we enclose revised monographs for insertion at page 812 of your current (1967) PDR. The nature and extent of the additions and other revisions in the enclosed monographs are emphasized by use of italics.

Sincerely,

ROBERT P. EWING,
Vice President, Marketing.

ORGANON INC.,
West Orange, N.J., October 27, 1967.

DEAR DOCTOR: The Food and Drug Administration has requested that we call your attention to the monographs for *Cortrophin® Gel, Cortrophin® Zinc, Hexadrol® Phosphate Injection and Hexadrol®* Tablets and Elixir in the current *Physicians Desk Reference.* The FDA considers these monographs to be incomplete in presenting necessary information for the safe and effective use of these drugs, and, therefore, potentially misleading.

To provide you with the necessary information, we enclose revised monographs for insertion in your *PDR.* The nature and extent of the additions and other revisions in the enclosed monographs are emphasized by use of italics.

Sincerely yours,

JOSEPH D. CUONO, M.D.,
Director, Professional Services.

E. R. SQUIBB & SONS INC.,
New York, N.Y., October 24, 1967.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to certain advertisements for Mysteclin ®–F products which the FDA regards as misleading. The main theme of the advertising, which we have stopped, suggests that "almost every candidate for broad-spectrum antibiotic therapy, is a candidate for Mysteclin–F."

We wish to emphasize that those patients selected for tetracycline therapy who are know to be particularly susceptible to candidal superinfection are the potential candidates for Mysteclin–F therapy.

The FDA points out that recent journal advertisements for these products suggested that candidal superinfection is a serious problem with the use of ampicillin. This was not supported by the reference used in the ads. Although the reference cited included the statement that candidal overgrowth may follow ampicillin therapy, the FDA has asked that we point out that the significance of this overgrowth has not been established.

Further, the same ads omitted important warning information relating to precautions and side effects. The nature and extent of the omission are capitalized in the enclosed "Brief Summary".

Sincerely,

SQUIBB.

ENDO LABORATORIES INC.,
Garden City, N.Y., October 14, 1967.

DEAR DOCTOR: Undoubtedly you are aware of the unfortunate widespread confusion which surrounds the recall which we are presently conducting of certain specific packaging lots of our Coumadin Tablets 2 mg., 2½ mg., and 5 mg.

We enclose:

1. A copy of a public statement issued yesterday, October 13, 1967, by James L. Goddard, M.D., Commissioner of Food and Drugs.
2. A copy of a letter which is today being sent to every hospital pharmacy, retail pharmacy and drug wholesaler throughout the country.

We, of course, also regret that this confusion has arisen, and we feel that the attached letters will reassure you and your patients concerning Coumadin.

Very truly yours,

LEONARD S. BRAHEN, M.D.,
Medical Director.

OCTOBER 13, 1967.

From: James L. Goddard, M.D., Commissioner of Food and Drugs.

There has been widespread confusion among heart patients, their physicians, and the public generally, since it was reported yesterday that approximately