

immediately suspend sale of this product and to withdraw existing stocks from the market.

It is the contention of the Food and Drug Administration that present evidence for Madricidin does not establish its safety and effectiveness in the treatment of the conditions for which it is recommended and that "hazards" accompanying its use outweigh potential benefits.

However, we should like to make you aware that ever since this preparation was marketed with the accord of the Food and Drug Administration in January 1959, it has been prescribed by physicians for more than two million patients. The Government's position apparently discounts the experience accumulated by thousands of physicians and the hundreds of thousands of patients that have benefited from its use. During the seven years that this product has been available, we have received reports of only five cases of side effects and no reports of Stevens-Johnson syndrome in patients treated with it.

While we believe firmly that the demands of the Food and Drug Administration are inconsistent with this outstanding record, we have no choice but to comply. This is preferable to exposing the physician, his patients, and our company to the possible detrimental effect of the only alternative, government legal action to remove the product from the market.

Recall of Madricidin from patients is not deemed necessary. However, your patients will not be able to refill their present supplies once they have been exhausted, and all samples of Madricidin in your possession should be destroyed.

We regret any inconvenience that this announcement or newspaper stories prior to this letter may have caused you and your patients, and pledge our continuing efforts to safeguard and constructively advance traditional manufacturer-physician-patient relationships.

Sincerely,

ROBERT E. DIXON, M.D.,
Director, Professional Services.

WARNER-CHILCOTT LABORATORIES,
Morris Plains, N.J., March 7, 1966.

DEAR DOCTOR: You may be aware of recent publicity concerning legal action taken by the Food and Drug Administration on February 28, 1966 with regard to Peritrate SA, the sustained action dosage form of Peritrate. In connection with this action we believe it is important to bring to your attention the following statement issued on March 4, 1966 by the Commissioner of the Food and Drug Administration:

"It has come to my attention that physicians are receiving calls from their patients asking whether or not they should continue to take Peritrate SA.

"The FDA has never indicated that this drug is unsafe for use for the treatment of angina pectoris and wishes to reassure both patients and physicians that the recent action by FDA against the product was related solely to advertising and other promotional claims made by the manufacturer."

We are gratified that the Food and Drug Administration has made clear that its action has nothing to do with the safety of Peritrate. This prompt action not only represents a fine example of cooperative working relations between industry and government but will serve to allay the fears of those of your patients who may have been calling you.

Peritrate® in all its dosage forms remains available for your prescription.

Sincerely,

FRANK DiTRAGLIA, M.D.,
Medical Director.

CIBA PHARMACEUTICAL CO.,
DIVISION OF CIBA CORP.,
Summit, N.J., February 16, 1966.

IMPORTANT DRUG RECALL

DEAR DOCTOR: CIBA Pharmaceutical Company has agreed, at the request of the Food and Drug Administration, to suspend sales of Elipten tablets and withdraw all existing stocks from the market. The Food and Drug Administration considers that there is a lack of substantial evidence that Elipten tablets are effective in the treatment of epilepsy; that it causes adverse reactions including