SUBJECT August 8, 1970 Federal Register Notices - Action & Responsibility Guidelines

DATE August 20, 1970

TO Dr. William F. Head
Dr. Aldo P. Truant

FROM Elwood A. Garner

IN REPLY TO

COPIES TO Isaac R. McCrew, Erwin P. G. Rehn, Giovanni Costa, Zarch Hadidian, L-9

The following is a summary of the action and responsibility guidelines hammered out during our conference on the subject in Rochester Wednesday, August 19, 1970. Also present and participating were Vincent Kleinfeld, our counsel on F & DA legal and regulatory matters, and Dr. Jean Mayer from Harvard, well known authority in the field of nutrition and most recently Special Assistant to the President of the United States for Nutritional Affairs and the continuing special consultant to us in matters of obesity and nutrition.

I. Required Action #1: --

By October 6, 1970 the Pharmaceutical Division must revise the labeling of its orally administered amphetamine and dextroamphetamine containing products to conform with the requirements set forth on pages 12652 and 12653 of the Procedural and Interpretive Regulations published in the Federal Register, Vol. 35, No. 154 -- Saturday, August 8, 1970.

Responsibility for carrying out this required action is assigned to Dr. William F. Head.

1. Specific products to be re-labeled are:

   a. Biphetamine '7½', '12½', and '20'.

   b. Biphetamine-T '12½', Biphetamine-T '20'

2. Indication and dosage information contained in the revised labeling shall be restricted to exogenous obesity and shall exclude narcolepsy and hyperkinetic behaviour disorders.

3. Our presently used dosage statement in labels and labeling shall be retained.

4. Re-labeling requires "slavish adherence" to the F & DA order that labeling of orally administered amphetamine and dextroamphetamine and their salts should be substantially as published in the August 8, 1970 Federal Register.