5. Disposition of other items: --

a. The word "amphetamine" is to replace the dl-amphetamine designation in new labels and labeling in line with the nomenclature used in the Federal Register notices.

b. 'Biphetacel' containing amphetamine and dextroamphetamine as phosphates is to be deleted as of October 8, 1970 or as much before that date as stocks may be exhausted. Sales and sales potential of the product are too insignificant to warrant retention in the line.

c. Injectible 'Raphetamine' Phosphate 1% is not an orally administered amphetamine product and therefore not subject to the August 8, 1970 order.

d. Mr. McGraw and Dr. Head are to make an immediate determination and recommendation with respect to the disposition of methamphetamine-containing products in the line, i.e., 'Bifran', 'Efroxine'. If retained on the market, the labels and labeling for these products must be brought into conformity with the provision of A.1. found on Page 12679 of the Federal Register notice of August 8, 1970. The only question to be resolved by the determination and recommendation of Mr. McGraw and Dr. Head is whether to delete these products as of October 8, 1970 or as of February 8, 1971.

II. Required Action #2: --

By February 8, 1971 the Pharmaceutical Division must submit in response to the implementation notice of August 8 new, previously unsubmitted data including that "from adequate and well controlled clinical investigations". In support of effectiveness claims for 'Biphetamine', 'Biphetamine-T', and 'Ionamin' now ruled as "Possibly Effective" by the F & DA.

Responsibility for Action #2 -- Dr. Aldo P. Truant and staff.