c. 'Ionamin'

(1) Short term anorectic effectiveness.

(2) Contribution of resination in terms of:

(a) Blood levels and bioavailability.

(b) Longer duration of effect.

(c) Advantages.

III. Some Pertinent Observations

1. Vincent Kleinfeld accurately confirmed the distinction between the "possibly effective" ruling for our drugs as contained in the implementation notice of August 8 from the "effective, but ...." observation contained in the NAS/NRC reports. As Vincent pointed out, the NAS/NRC "effective, but...." observation as opposed to the "possibly effective" ruling by the F & DA could be of value in a court but was otherwise meaningless to us since we have no choice but to comply with the "possibly effective" F & DA ruling.

2. In the new label copy for 'Biphetamine-T' under "Actions" Jean Mayer laid the foundations for a statement with respect to the contribution of Tuazole to 'Biphetamine-T' expressed along these lines --- "Biphetamine-T produces an anorectic effect which diminishes after a few weeks. Patients may experience less irritability than with amphetamine alone".

3. The wisdom of caution and the critical importance of "slavish adherence" to the August 8, 1970 implementation order published by the F & DA were heavily underscored by Vincent Kleinfeld.

4. It was concluded that each strength of our products be included in studies.

5. It was unanimously agreed that every effort should be made in line with Aldo Truant's thinking to get the thinking of the appropriate F & DA officials with respect to satisfactory objectives and the protocols themselves. The suggestion that the PMA be asked to help bring to the attention of the F & DA the importance of giving manufacturers such as ourselves the benefit of their attention with respect to our protocols will be pursued. But we shall have to rely primarily upon Aldo Truant, Giovanni Costa, to glean some guidelines from F & DA officials.