

KESINGER AND KAPLAN

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not classifiable as amphetamine or amphetamine salts within the reasonable and proper factual meaning of those terms and that no other term used in the May 26 proposal was applicable to either of the Biphphetamine products.

On June 21, 1971, a representative of the Bureau notified Pennwalt that, contrary to the position taken by Pennwalt, it was the Bureau's conclusion that the scope of the term "amphetamine salts" did in fact encompass the resin complexes contained in the Biphphetamine preparations and accordingly, that Biphphetamine and Biphphetamine-T were presently subject to Schedule III classification and, under the May 26 proposal, Biphphetamine and Biphphetamine-T would become subject to Schedule II classification if the proposed transfer were to be accomplished.

As a consequence of the nature of the controls imposed upon Schedule II controlled substances, the manufacture and distribution of Biphphetamine and Biphphetamine-T would be severely and unnecessarily restricted were the proposal, as interpreted by the Bureau, to be made into a final regulation. Such restrictions would be to the substantial detriment of Pennwalt, medical practitioners, and patients who are presently being benefitted by these safe and effective anorectic drugs.

It is respectfully submitted that a hearing on the record as provided for in Section 201(a) of the Act and Sections 4 and 7 of the Administrative Procedure Act [APA] (5 U.S.C. §§553 and 556)