MATERIAL ON PENWALT CORP. FROM FILES OF DRUG ENFORCEMENT AGENCY, DEPARTMENT OF JUSTICE

[redacted]

CORPORATION

PRESCRIPTION PRODUCTS

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August 13, 1970

ALL FIELD SALES PERSONNEL

You undoubtedly have read in your newspapers that the Food and Drug Administration has officially published a general policy statement for anoretic drugs. As we have experienced in the past, lay press reporting of such information is not always an accurate interpretation of the Food and Drug Administration's publications. In this bulletin we will attempt to pass along to you, (1), the facts concerning our particular products - Biphetamine, Ionamin and Biphetamine-T, and (2), information concerning all other amphetamines.

1. Biphetamine, Ionamin and Biphetamine-T

The drug admendments of 1962 require that any marketed drug with an NDA approved during the period 1938-1962 had to submit data regarding efficacy. The reason for this was that prior to the drug regulations of 1962, the Food and Drug Administration was only concerned with the safety of the drug and not the efficacy of the drug. Since Biphetamine, Ionamin and Biphetamine-T were "NDA'd drugs", we submitted efficacy data in September of 1964. The Food and Drug Administration did not have sufficient personnel to review this data and contracted with the National Academy of Sciences and the National Research Council to review the efficacy data. The Food and Drug Administration has just made public the evaluation of the academies with regard to Biphetamine, Ionamin and Biphetamine-T. All three products were ruled "possibly effective" for the treatment of obesity. The regulations state that any drug ruled as "possibly effective" may continue on the market and the manufacturer is required to submit new data to establish the efficacy of the product within a six month period from the time of the announcement (August 5, 1970).