controls, and (2) amphetamines (including the company's Biphetamine products) are required to be phased out of production by the end of a 180-day period, commencing as of January 14, 1972. These two developments were anticipated by the company's Mexican operations when budgeting, last November, Biphetamine sales for 1972 of only $100,000.

(5) In November, 1971, the company's United States operations budgeted Biphetamine sales in the U.S. in 1972 based on the domestic regulations then (and still) in effect, at a level substantially lower than the company's 1971 sales of Biphetamine products.

(6) The budgeted export of Biphetamine (either resin or finished capsule) from the United States in 1972 did not include any projected export to Mexico. As to all other existing or anticipated exports of Biphetamine products from the United States in 1972, the total amounts involved are and were not significant in dollars, units of weight, or numbers of capsules.

Mr. Drake stated, further, that the continuing study will review specifically the amount and distribution of Biphetamine product sales in Mexico during the past several years, in order to ascertain whether there has been any failure on the company's part, through any of its representatives at any level, to maintain effective internal controls against diversion of the company's products into other than legitimate channels.

Mr. Drake stated that it is the company's intention to cooperate fully with the United States government in order to make certain that all appropriate actions by the company and any of its representatives may be taken to further our common interest in proper regulation and control of Biphetamine. He added that its use as a prescription pharmaceutical has been established for many years in the United States as well as in many foreign countries, including Mexico.

TELEPHONE COMMUNICATION

JANUARY 27, 1972.

To: FDA Memo File.
From: W. F. Head, Jr.

On January 26, 1972, a return telephone call was placed to a Dr. Alvin Gardner of the Division of Neuropharmacology, FDA. He had previously contacted Dr. Truant requesting amphetamine quota information.

In his absence Dr. Barrett Scoville of FDA received the call and requested the information following.

Dr. Scoville was given the general provisions including the complete list of drugs covered by the new Mexican law. He was informed that amphetamines were not outlawed by this act but rather were placed in a narcotic category. He was also informed that we had stopped shipping Biphetamina and Biphetamina-T until such time as we could clarify the exact narcotic requirements (forms, etc.) with the proper authorities in Mexico. He did not question nor was information volunteered concerning specific letters directed to us by the Mexican government concerning Biphetamine and Biphetamine-T.

Dr. Scoville questioned how we knew that our shipments were intended for legitimate medical and scientific purposes. He was informed that all of the regulatory requirements were met by our firm and that we dealt through wholesalers only for 95 percent plus of our business. It was indicated that we knew most, if not all, of our wholesale customers personally and that their BNDD number was on file for the proper schedule of drug ordered. This BNDD number is in the computer with programming to prevent the writing of any order if the BNDD number and proper schedule is not available. Furthermore, a proper BNDD order blank is required for filling orders for Biphetamine and Biphetamine-T. To his further inquiries concerning our knowledge of legitimate movement at the physician level, he was informed that in an extra-regulatory manner we do perform prescription audits using DKK (IMS) and compare these independent figures to our own sales figures. He was informed that these independent audits check very closely with our sales figures. Finally, it was indicated to Dr. Scoville that we also utilize a data processing physicians call report system whereby physicians profile information including prescribing habits can be obtained.

Dr. Scoville wanted to know how we had arrived at our quota request and what the present needs are for amphetamine. The procedure we followed in making our request on October 15, 1971, was covered in detail with him including the 50 percent inventory allowance stated in the regulations.