ment of Narcotics within the U.S. Treasury Department were assigned to the Department of Justice. This Justice Department enforcement agency is now known as the Drug Enforcement Administration.

The 1970 Controlled Substances Act established categories of drugs in five schedules of gradation, and the FDA and DEA cooperate with respect to specific scheduling thereunder. The FDA's role under the Federal statutory and regulatory scheme is to make a determination of the benefit-risk status and the effectiveness of particular drugs. The FDA has determined that Pennwalt's Biphetamine is safe and effective as an adjunct in the short-term management of obesity. As you know, the DEA has assigned it to schedule II. Similarly, the FDA has determined that Pennwalt's Ionamin is safe and effective. The DEA has assigned it to schedule IV.

The 1970 law also imposes stringent accounting, reporting and production requirements, extensive labeling requirements, registration of manufacturers, distributors and dispensing entities, elaborate requirements for safekeeping of controlled substances, and establishes other procedures for the control and supervision of controlled substances.

With respect to the manufacture of our schedule II product, Biphetamine, we must receive a quota allocation from the DEA, annually. That quota establishes the amount of amphetamine base (our raw material) which will be available to us for the relevant calendar year. In this process, Pennwalt:

1. Must have submitted before the close of each year a formal quota application for the forthcoming year, setting forth our raw material utilization for the preceding 3 years.

2. Upon receipt from the DEA, early in the new year, of a quota allocation—which generally does not afford a full calendar year of supply—we operate thereunder.

3. Several months later, as our inventory diminishes, we must make a further formal request for an additional quota allocation.

4. That request must contain:

(1) a statement of current total plant inventory;

(2) projected utilization to yearend at our current usage rate;

(3) a resultant computation of the additional allocation we require; and

(4) such other information as is appropriate to aid the DEA in its evaluation, including, for example, the following: (*a*) Comparisons of our distribution, stated in terms of kilos; (*b*) International Marketing Service—IMS—audits of drugstore purchases and prescription utilization; and (*c*) Wholesale distribution inventory level analysis.

As a result of the quota process I have described, we are supplied with a raw material base generally sufficient to meet our actual annual demand. However, we do not receive a quota allocation adequate to guarantee us that in fact we will be able to complete production for that calendar year.

As is evident, this rigorous quota control program is an essential part of the regulatory design to insure that the product originates and remains in legitimate channels of manufacture and distribution.

The proper scheduling of Ionamin—phentermine—has been under review by the DEA since early 1973. At that time, Pennwalt advised