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 ensure 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 the DEA that it would not oppose Schedule III classification for Ionamin if related, competitive products were similarly scheduled. Pennwalt took this position in a spirit of cooperation, although Pennwalt remains unaware of any evidence that would support the Schedule III classification proposed by the DEA. The matter remains pending, with Ionamin in Schedule IV awaiting further action by the DEA, following its receipt of Pennwalt's lengthy documentation of the scientific and other facts we deemed relevant to the question.

In this connection, it should be noted that Pennwalt advised the DEA on November 17, 1975, that:

> "Phentermine (i.e. Pennwalt's Ionamin) has been marketed in the United States since approximately 1959. During the sixteen (now seventeen) years since then, approximately five hundred million (500,000,000) dosage units of Ionamin have been prescribed by physicians for use by a diverse patient population, ranging from young adults to the aging, a population necessarily including a broad spectrum of emotional, mental and physical characteristics.