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, that is Pennwalt's Ionamin, has been marketed in the United States since approximately 1959. During the 16 (now 17) years since then, approximately 500 million 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.
>
> In all of those 16 years, Pennwalt has learned of no deaths or any serious physical or mental injury or damage attributable to the drug. In addition, Pennwalt is not aware of any significant instances of phentermine abuse, and its product liability experience with the drug Ionamin reflects but one payment, in the amount of $3,500, to settle one suit brought by a patient who alleged she had used Ionamin (on prescription) as well as several other drugs manufactured by other defendants in her case.

THE DEA MONITORS AND AUDITS THE DISTRIBUTION OF ANTIOBESITY DRUGS

The Drug Enforcement Administration plays a very active role in monitoring and auditing our scheduled substances. It requires that all manufacturers of all schedule II products submit monthly DEA–222–C forms. These reports require Pennwalt; for example, to list each purchase or sales transaction involving Biphetamine, as a schedule II substance, by date, amount, and identity and location of purchase.

The DEA also requires the quarterly filing of ARCOS computer tapes recording each controlled substance transaction under schedule II and all transactions involving narcotic drugs in any schedule exclusive of those on schedule V. These computer tapes show the movement of the drug both within the plant and in distribution, again showing date, amount, and recipient.

For Ionamin, a schedule IV product, the DEA requires that we record the name and location of each purchaser, its registration number, and the quantity, identity, and strength of the product by package unit. These same standards apply to our purchase of Ionamin's raw material, phentermine.

In addition, the DEA requires a separate listing of all controlled substance transactions, segregated from all other company records, to facilitate ready inspection by DEA representatives.

Separate reports of any suspected loss in transit, whether or not confirmed, and any other significant loss of any scheduled drug, are reported to the DEA immediately. If any suspected loss is not accounted for, followup reports are made.

The DEA also conducts periodic, formal audit inspections of Pennwalt's entire system of accountability for all schedules of controlled substances. Apart from these audits, DEA representatives are on our premises on a regular basis in the routine performance of their duties,