



R. Weinstein of Texas

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May 17, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Dear Sir or Madam,

RE: Docket Nos. 92N-0297 and 88N-0258

We are a licensed prescription drug wholesaler doing business in Texas and Hawaii.

We purchase our inventory through several of the major full-line wholesale distributors.

We purchase approximately 50% of our inventory from smaller wholesale distributors who, in some cases, are not authorized distributors for the products they sell.

We purchase directly from only 4 drug companies.

We do not receive prescription drug pedigrees from full-line wholesalers or from manufacturers.

If we were required to provide prescription drug pedigrees that go back to the manufacturer to our customers, we could do so only in those instances where we have purchased directly from the manufacturer or purchased from an "unauthorized distributor" who is able to provide that complete information to us. However, those "unauthorized distributors" will not be able to do so unless they purchased directly from the manufacturer, which is rarely the case. Since we do most of our business with major full-line wholesalers who do not provide any pedigrees, and because most "unauthorized distributors" will not be able to provide pedigrees back to the manufacturer, we will not be able lawfully to engage in 70% of the transactions we now engage in.

Our company services over 600 physicians/clinics.

88N-0258

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Our customers do not do business with any of the major full-line wholesalers and to force them to have to do so would disrupt the entire distribution system.

Our customers will be adversely affected if we are not able to supply them.

In many cases, it is not practical to become authorized distributors for certain manufacturers due to the fact that drug wholesalers can provide next day delivery without requiring case quantity minimum purchases.

Our company employs 15 people who will be put out of their jobs if the prescription drug pedigree requires that transactions be reported back to the manufacturer.

We support a return to the guidance issued by FDA in August 1988 with respect to prescription drug pedigrees and authorized distributors.

Sincerely yours,

A handwritten signature in cursive script that reads "Richard A. Weinstein".

Richard A. Weinstein, R.Ph.
President

CROSS FILE SHEET

FILE NO: 88N-0258/C87

SEE FILE NO: 92N-0297/74