

AK DISTRIBUTORS

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May 23, 2000

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

Dear Sir/Madam:

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

- We are licensed prescription drug wholesalers doing business in 8 states.
- We purchase some of our inventory through one of the major full-line wholesale distributors.
- We purchase approximately 70% 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 15 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 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 80% of the transactions we currently engage in.
- Our company services over 500 retailers, physicians and clinics.
- All of our customers have advised us that their business would be adversely affected if we are not able to supply them.
- We have tried to become authorized distributors but our requests have been turned down by the majority of manufacturers.
- Our company employs 14 persons 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,



Eugene Braddy R.Ph.
President

92N-0297

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