



May 11, 2000

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

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

Dear Sirs:

We are a licensed prescription drug wholesaler doing business in 16 states. We purchase some of our inventory through one of the major full-line wholesale distributors and approximately 50% of our inventory from smaller wholesale distributors who, in some cases, are not authorized distributors for the products they sell.

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 some of our business with major fill-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 50% of the transactions we now engage in.

Our company services over 2,300 physicians and veterinary customers. We have spoken with a number of these customers and they do not presently do business with any of the major full-line wholesalers. One hundred percent of our customers have advised us that their business will 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. Our company employs 10 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 Yours,

A handwritten signature in cursive script that reads 'David Trumell'.

D & H Wholesale Medical, Inc.

88N-0258

C83

CROSS FILE SHEET

FILE NO: 88N-0258/e83

SEE FILE NO: 92N-0297/e70