

Supreme

DISTRIBUTORS
COMPANY

May 25, 2000

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Dockets Management Branch
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No's 82N-0297 & 88N-0258

Dear Sir/Madam:

Supreme Distributors has been a licensed pharmaceutical wholesaler for more than 13 years and we currently hold wholesale drug distributor licenses from 39 states. We are fully compliant with all of the applicable provisions of the PDMA, and have built our distribution system with the highest levels of controls as it relates to product security and record keeping.

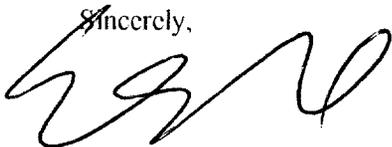
All of our product is purchased from sources who are properly licensed, but many of them are not "authorized distributors" for the items they sell us, as defined by the PDMA. All of our sources also produce the proper pedigrees to support the merchandise they sell us, based upon the pedigree requirements that the industry has been operating under for the past twelve years. Their ability to continue to do this will be all but eliminated if the proposed regulations go into effect.

In our thirteen plus years of doing business, we can't recall any instance where compliance with the pedigree requirements has been instrumental in assuring the quality of the goods being distributed. It is our belief that quality assurance is influenced more by adherence to the state licensing requirements, not by adherence to the drug pedigree requirements.

Concerning the practicality of the new pedigree requirements, we believe that it will be virtually impossible for non authorized distributors to comply, which will not only put them out of business, but will severely impact their customers who will no longer be able to purchase from these non authorized distributors. Adherence to the proposed regulations will totally disrupt the wholesale drug distribution process, and have a devastating effect on the wholesale industry, which will ultimately result in higher prices to the consumers.

Therefore, for all of the reasons mentioned above, we are requesting the FDA return to the guidance issued in August 1998 with respect to drug pedigrees and authorized distributors.

Sincerely,



Sal Ricciardi
President