



Rebel Distributors Corp.

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May 12th 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

Rebel Distributors is a licensed pharmaceutical wholesaler in over thirty states, and a company that has been in business since 1984. We have followed the guidelines as stipulated in the 1988 Prescription Marketing Act {and subsequently finalized in 1994} as required, with extreme vigilance.

It is our opinion, and one shared by our entire industry of wholesalers and retailers, that the original concerns and objectives of the act have clearly met their goals. We now have in place very thorough and extremely high standards. All aspects of quality control as well as the integrity of all pharmaceutical products in the wholesale distribution industry are always maintained at the highest levels.

Our experience has clearly shown us that the pedigree requirements, {as proposed in the newest version of the Prescription Drug Marketing Act}, will have little or no beneficial effect as to the integrity of pharmaceutical products as a whole.

As proposed, the latest requirements that we obtain "letters of authorization" from all manufacturers, and a requirement that we "provide drug pedigrees that go back to the manufacturer", will be incredibly burdensome and in many cases impossible to facilitate. The effect would be *catastrophic* to customers suppliers and us. In many cases, our suppliers would be put out of business overnight. As well, our customer's inability to buy from us, and other wholesalers like us, would result in lower profits and inevitably *higher prices to the consumers*.

We ask, that on behalf of our company, and many other pharmaceutical retailers and wholesalers, that the FDA *return to the guidance issued in August 1988 with respect to drug pedigrees and authorized distributors*.

Sincerely, Ronald Ressler

Ronald Ressler
President, Rebel Distributors

Cc: Steve Simms
Sal Ricciardi

88N-0258

C82

CROSS FILE SHEET

FILE NO: 88N-0258/C82

SEE FILE NO: 92N-0297/C69