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**VIA FACSIMILE &
FEDERAL EXPRESS**

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
5600 Fishers Lane, HFD-5
Rockville, MD 20857

Re: FDA Request for PDMA Information

Dear Ms. Axelrad:

Thank you for the opportunity to provide AmeriSource's position regarding the Agency's regulations implementing PDMA. Below are AmeriSource's answers to the five questions you submitted.

- 1. At the Agency's Part 15 Hearing on October 27, 2000, we heard representatives of wholesalers of prescription drugs say that the largest wholesalers would oppose the requirement of a universal pedigree. Please state whether you would favor or oppose such a requirement and why.*

AmeriSource Corporation ("AmeriSource") is opposed to the requirement of a universal pedigree. The existing system for the distribution of prescription drugs is safe, efficient and already highly regulated. Wholesale drug distributors must be licensed in every state in which a facility is located and their facilities are subject to inspections by both state and FDA officials. Drug distribution is also subject to extensive regulation and inspection by DEA, OSHA and EPA. All drug distributors are licensed by the states under PDMA requirements that include detailed storage and handling requirements, specific procedures for inspecting and accepting product into inventory and detailed record keeping relating to the receipt and disposition of prescription drugs. AmeriSource limits the number of unauthorized suppliers it uses to those that have demonstrated their ability to meet PDMA's requirements. Additionally, authorized distributors, such as AmeriSource, are required to maintain in their files, subject to FDA inspection, any pedigree information provided by unauthorized distributor suppliers.

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Unauthorized distributors also can be cited under PDMA for failing to maintain the necessary documentation when they sell products. In addition, current FDA regulations provide FDA with sufficient means to investigate any problems related to product source or quality, such as suspicion of counterfeit, expired, adulterated or misbranded drugs. The current practice under PDMA, which has worked well for 12 years, requires unauthorized suppliers to provide pedigree information back to the authorized distributor or the manufacturer. This practice is sufficient to provide the appropriate accountability under PDMA.

Full service drug distributors, such as AmeriSource, operate efficiently on razor thin margins (less than 1%) to provide the health care industry with a wide range of safe products and services. Wholesale distributors help to increase product availability, deliver needed drugs with "just in time" service (either same day or next day depending on the customer's needs) and reduce the overall number of transactions required in the distribution of prescription drugs, thereby saving the healthcare industry billions of dollars in transaction costs. The key to AmeriSource's ability to provide such beneficial products and services in a cost effective manner is efficiency. The imposition of a universal pedigree requirement would be cost prohibitive by interfering with AmeriSource's ability to operate efficiently. Each of AmeriSource's 23 distribution centers carries between 20,000 and 30,000 individual products (or SKUs), about half of which are prescription drugs. Each of its distribution centers can process between 20,000 and 80,000 order lines per day. In order to meet a universal pedigree requirement, AmeriSource would have to capture and track specific lot numbers and expiration dates for each of the almost 15,000 prescription drugs its distribution centers carry as well as store those products by separate lots in separate locations and continue to track the product through each sale. AmeriSource does not segregate product by vendor or customer as would be required in order to comply with a universal pedigree requirement. Much of the work needed to perform these functions would have to be done manually, because the manufacturers' barcodes do not indicate lot numbers. AmeriSource currently does not handle prescription drugs in this manner and the costs and loss of efficiency associated with implementing these procedures would be enormous. These added costs would then have to be passed on to AmeriSource's customers, and, ultimately, consumers. In addition, the requirement would almost certainly reduce or eliminate AmeriSource's ability to provide healthcare products within the present "just in time" fulfillment cycle

2. *We understand that there are computer software and systems readily available that can be used to create a pedigree. What do you believe it would cost to create a pedigree and provide it with the drugs that you sell? What would these costs be associated with specifically? Do you believe these costs could be accommodated without a significant increase in the cost or decrease in the availability of prescription drugs?*

While it is true that there may be computer software available that could be used to create a pedigree, for the reasons discussed above complying with a universal pedigree requirement would be a tremendous and extremely costly logistical burden. As a threshold matter, the "marking" requirements necessary to create an efficient data collection and maintenance process that would be required for a universal pedigree do not exist today in the distribution channel. Although AmeriSource cannot estimate the exact cost of implementing a universal pedigree requirement, it would be very significant. The specific costs are addressed in response to question one and involve the integration of pedigree requirements across the distribution spectrum from sale by the supplier to sale to the customer. As explained above, AmeriSource believes that the added costs and loss of efficiency that would be caused if a universal pedigree requirement is imposed could not be accommodated without a significant increase in the cost or decrease in the availability of prescription drugs. AmeriSource's added cost and loss of efficiency will be passed on to its customers and the ultimate consumers through higher prices. Further, as noted above, the process would almost certainly eliminate AmeriSource's ability to provide the "just in time" next day fulfillment cycle that our customers have come to expect.

3. *Do you believe it would be advisable to eliminate the pedigree requirement altogether? Please explain your answer.*

Because drug distributors are already so heavily regulated under both state and federal law and the pedigree information may be redundant of other required records, AmeriSource believes that eliminating the pedigree requirement would not result in harm to public health and safety. However, AmeriSource supports maintaining the drug pedigree as it has been used under PDMA for the past 12 years as part of the overall current regulatory framework that provides the public with a safe and efficient drug distribution system.

4. *Do you believe there would be any consequence to the public health and safety if the pedigree were eliminated?*

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As stated above, AmeriSource believes that the current regulatory framework at both the state and federal level, including the drug pedigree requirement that has been in place since 1988, is more than adequate to protect the public health and safety.

5. *What would your position be on the following requirement? All distributors (authorized and unauthorized) must maintain and pass on a pedigree for those prescription drugs that are bought from or sold to a secondary distributor.*

Because AmeriSource does not segregate product by vendor or customer and to do so would involve the logistical burdens and costs discussed above, AmeriSource would be opposed to such a requirement.

Please contact me if AmeriSource can be of any additional assistance in this matter.

Yours truly,


William D. Sprague

WDS:fmr