



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Diane Goyette, Esq.
Director of Regulatory Affairs
National Wholesale Druggists' Association
1275 K Street, N.W., Suite 1212
Washington, D.C. 20005-4006

Dear Diane,

Thank you for offering to facilitate our communication with the five primary wholesalers so that we can get their views on the record regarding the Agency's regulations implementing the Prescription Drug Marketing Act .

Pursuant to our conversations, I am sending you the enclosed questions to be forwarded to the five primary wholesalers. It would be very helpful if they could forward their answers directly to me at the address below.

Please emphasize that the answers will be placed in the docket and become a part of the public record. In addition, because our report to Congress is due January 15, 2001, I would appreciate their responses as soon as possible.

Sincerely,

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

Enc.

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Questions on PDMA for the Primary Wholesalers

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.
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?
3. Do you believe it would be advisable to eliminate the pedigree requirement altogether? Please explain your answer.
4. Do you believe there would be any consequences to the public health and safety if the pedigree were eliminated?
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.