The
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Randolph J. Friedman
Chairman and Chief Executive Officer

December 21, 2000

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

Dear Ms. Axelrad:

At the suggestion of Dianne Goyette attached please find my answers to the questions that you posed regarding the Agency's regulations implementing the Prescription Drug Marketing Act.

Harvard is a national wholesaler that is active in buying and selling in the secondary market. Should you have any questions, please do not hesitate to contact me.

Very truly yours,

Randolph J. Friedman

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ANSWERS

1. *As to question number one, we oppose the requirement of a universal pedigree. The cost implications of such a pedigree are very significant to our company and in all likelihood would layer on so much additional cost that it would be difficult for us to operate successfully within our current economic perimeters. You must recognize that the use of a pedigree complicates the receiving process, the pulling process, the shipping process, and the stocking process. It places unnecessary burdens on our regulatory compliance, which is already exaggerated in relationship to the size of our business.*

2. *In response to question number two, for a company our size computer software additions are often times beyond our financial ability. Already our business is highly automated and our existing software is a highly customized product. Any effort to layer upon that software an entirely new system designed to accommodate the new pedigree standards would potentially be impossible to comply with and overall raise our cost of business prohibitively.*

3. *As to question number three, we agree with the NWDA's position to allow for a continuation of the way the authorized distributor and drug pedigree elements of PDMA have been put into practice over the last 12 years.*

4. *In response to question number four, at this point the Public Health and Safety has been assured by 12 years of activity under the current regulatory regime. Therefore, continuing with the current requirements should have no consequences to public health and safety.*

5. *Finally, as to question number five, I believe that this position would present the same significant difficulties that would be experienced under a universal pedigree. You must remember that we process literally thousands upon thousands of transactions everyday and therefore a partial burden is just as significant as a complete burden.*