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November 3, 2000

Seth S. Ray, Esq.
Associate Chief Counsel for Drugs
Office of the Chief Counsel
Food and Drug Administration (GCF-1)
5600 Fisters Lane
Rockville, MD 20857

Re: PDMA Final Rule: Effective Date; 65 Fed. Reg. 25639 (May 3, 2000).

Dear Mr. Ray:

We are writing you on behalf of the Pharmaceutical Distributors Association with respect to the application of the October 1, 2001 delayed effective date for 21 C.F.R. §§ 203.3(q)j 203.50. As Sal Ricciardi and I stated at the hearing last Friday, how the effective date is deemed by the Administration to apply to prescription drugs in interstate commerce before the effective date is important to the businesses of our members.

It is our Association's position that the delayed effected date should be interpreted to apply to prescription drugs first introduced into interstate commerce on or after the October 1, 2001 delayed effective date. Such an interpretation would be wholly consistent with the Administration's interpretation of the application of effective dates to labeling and other non-safety related requirements regarding regulated products. Rarely, and hardly ever, has the Administration imposed a regulation in such a way that it would cause products lawfully introduced into commerce to become unlawful at a later time. Accordingly, it is our view that this request is reasonable and does not set a precedent that would adversely impact the Administration's general mission.

We appreciate the opportunity that was afforded last week for our Association and others to present their views with respect to the issues set forth in the September 15

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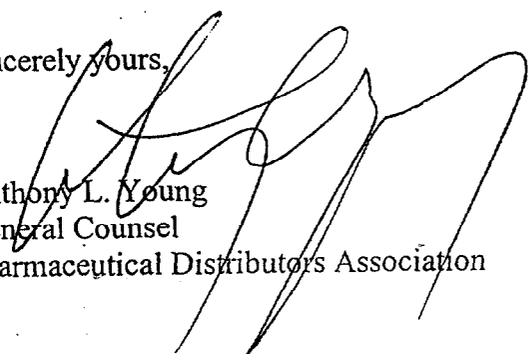
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Federal Register notice. We believe the dialog was useful and that the questions raised by the Administration's panel important issues. If you or your colleagues have other questions, please call me. Our Association is committed to responding to and addressing concerns or issues regarding wholesale drug distribution.

As we stated at the hearing, we request a response on the application of the effective date issue by January 15, 2001. If this is not possible, we would appreciate a communication from you as to why it is not possible. Our goal has been and continues to be to achieve an administrative resolution of this matter.

Again, thank you very much for last week's important dialog and the courtesies extended to me and the others in attendance.

Sincerely yours,



Anthony L. Young
General Counsel
Pharmaceutical Distributors Association

ALY/slj

cc: June Axelrad (HFD-005)
Sal Ricciardi
Lyle S. Genin