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July 24, 2001

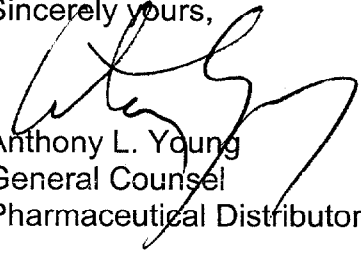
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket Nos. 92N-0927 and 88N-0258

To Whom It May Concern:

Please file the enclosed letter in the above-captioned docket. Thank you very much.

Sincerely yours,


Anthony L. Young
General Counsel
Pharmaceutical Distributors Association

ALY/jek
Enclosure

92N-0297

SUPI



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July 24, 2001

REGULAR MAIL

Ms. Jane S. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration (HFD-5)

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

RE: PDMA Wholesale Distribution Regulations

Dear Ms. Axelrad and Mr. Ray:

This is a follow-up to the Petition for Stay that was filed July 12, 2001 by the Pharmaceutical Distributors Association (PDA) with the Dockets Management Branch in Docket Nos. 92N-0927 and 88N-0258. Enclosed herewith is a copy of the July 20, 2001 letter sent by the below listed trade associations to the Acting Principal Deputy Commissioner in support of the PDA's request for a stay:

American Pharmaceutical Association
American Veterinary Distributors Association
Food Marketing Institute

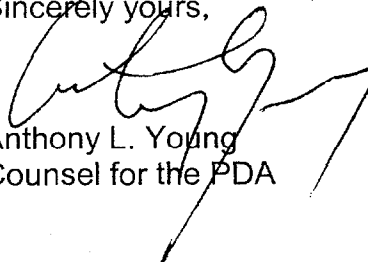


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Ms. Jane S. Axelrad
Seth S. Ray, Esq.
July 24, 2001
Page 2

Health Industry Distributors Association
International Academy of Compounding Pharmacists
National Community Pharmacists Association
National Association of Chain Drug Stores
Healthcare Distribution Management Association

Sincerely yours,



Anthony L. Young
Counsel for the PDA

ALY/jk

July 20, 2001

Dr. Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Schwetz:

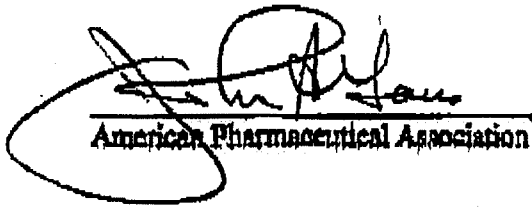
The trade and professional associations whose representatives have signed on the signature page attached to this letter are writing to express their strong support for the Petition for a continuation of the stay in the effective date of the Food and Drug Administration's Final Rule on the Prescription Drug Marketing Act (PDMA) relative to two particular drug wholesale provisions. The Petition was filed by the Pharmaceutical Distributors Association on July 12, 2001.

A further extension of the effective date of this regulation would provide the Congress with the time necessary to complete consideration of legislation designed to modify these two wholesale provisions. H.R. 68 and S. 1132, which have been introduced in the House and the Senate respectively, have well over 60 sponsors between them, which is reflective of the serious attention that the Congress is directing toward this matter. However, under the current effective date, the Congress clearly cannot complete legislative action in time to prevent thousands of distributors from liquidating their inventories, which will become practically unsaleable under the FDA Rule.

Since the FDA has recently reported to the Congress that the agency lacks the legal authority to make significant changes in its Final Rule, the Congress must enact new legislation to prevent the regulation from driving out of business thousands of small distributors and negatively impacting the operations of many other larger wholesalers.

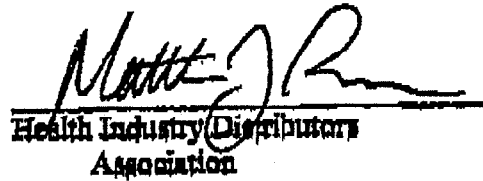
We are unaware of any significant health or safety concerns that would arise from a further delay in the rules implementing these two provisions, which were originally enacted into law over 13 years ago.

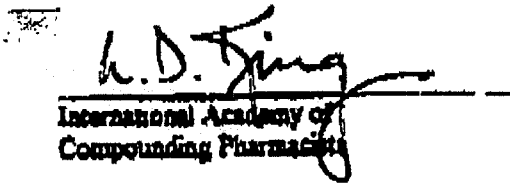
Thank you for your consideration of this request.


American Pharmaceutical Association

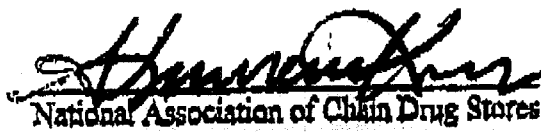

American Veterinary Distributors Association


Food Marketing Institute


Health Industry Distributors Association


International Academy of Compounding Pharmacists


National Community Pharmacists Association

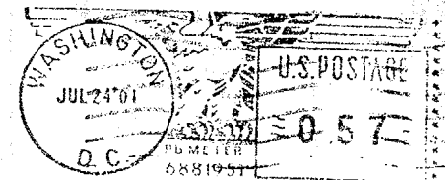

National Association of Chain Drug Stores


Healthcare Distribution Management Association



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