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August 7, 2001

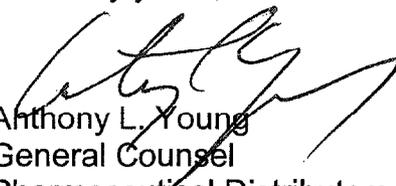
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

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

To Whom It May Concern:

Please accept for filing the enclosed letter of August 1, 2001 to the Acting Principal Deputy Commissioner supporting the petition of the Pharmaceutical Distributors Association for a continued stay of certain Prescription Drug Marketing Act regulations. The letter is signed by fifteen Members of Congress.

Sincerely yours,


Anthony L. Young
General Counsel
Pharmaceutical Distributors Association

ALY/jek
Enclosure

cc: Ms. Jane Axelrad (HFD-5)
Mr. Seth B. Ray (GCF-1)
(w/ enclosure)

88N-0258

SUP2

Congress of the United States

Washington, DC 20515

August 1, 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:

We would like to express my 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), filed by the Pharmaceutical Distributors Association on July 12, 2001. This narrow request only pertains to two specific elements of the agency's rules relating to prescription drug distributors. Previous rulemakings have already established a comprehensive state licensing system for all drug wholesalers, including minimum standards for the storage and handling of drug products as well as a detailed record keeping system.

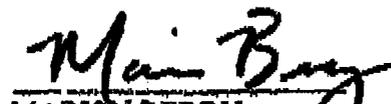
Since it took the FDA more than six years to propose, and over 11 years to finalize, the regulations in question, and their effective date have already been extended twice, there can be no argument that health or safety concerns preclude a further extension. On the other hand, it is uncontested that the implementation of these two provisions as currently written would have a serious adverse impact on, and probably drive out of business, several thousand small and medium sized drug wholesalers across America.

In its June 2001 Report to the House Appropriations Committee, the agency has clearly stated that it believes that its ability to make major changes in one of the provisions of its Final Rule is severely limited by the language of the statute and any such changes would require the enactment of new legislation. The requested stay will give the Congress time to consider such legislation, which has been introduced in both the House and the Senate and is already sponsored by well over 60 Members of the two bodies.

We also urge the FDA to move quickly on this request. The issues are, by now, well known to the agency and the wholesale industry will have to liquidate inventory beginning this Fall unless the stay is extended before then.

Sincerely,


JO ANN EMERSON
Member of Congress


MARION BERRY
Member of Congress

Robert Wexler
ROBERT WEXLER
Member of Congress

Tom Allen
TOM ALLEN
Member of Congress

Tom Tancredo
TOM TANCREDO
Member of Congress

Ron Paul
RON PAUL
Member of Congress

Dan Burton
DAN BURTON
Member of Congress

Frank Mascara
FRANK MASCARA
Member of Congress

Peter DeFazio
PETER DEFAZIO
Member of Congress

Mac Thornberry
MAC THORNBERRY
Member of Congress

Robert Andrews
ROBERT ANDREWS
Member of Congress

Mike Simpson
MIKE SIMPSON
Member of Congress

Tony Hall
TONY HALL
Member of Congress

Louise Slaughter
LOUISE SLAUGHTER
Member of Congress

Dennis Moore
DENNIS MOORE
Member of Congress