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August 9, 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 from Senators Mike Crapo and Charles Schumer of August 7, 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.

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)

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88N-0258

Congress of the United States

Washington, DC 20515

August 7, 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 write in support of the request by the Pharmaceutical Distributors Association for a continuation of the stay in the effective date of the Food and Drug Administration's (FDA) final rule on the Prescription Drug Marketing Act (PDMA). As you know, this 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.

The regulations in question took eleven years to finalize and the effective date has already been extended twice. It is highly unlikely that a further extension would pose a health or safety risk to the public. However, there are serious concerns remaining that implementation of these regulations would have an adverse impact on potentially thousands of small and medium-sized drug wholesalers across America.

The FDA has indicated to Congress it believes its ability to make major changes in one of the provisions of its final rule is limited by the language of the statute and any such changes would require the enactment of new legislation. The requested stay will give Congress time to consider such legislation, which has been introduced in both chambers of Congress.

Thank you for your consideration of this issue. Your prompt attention to this matter would be appreciated.

Sincerely,

Mike Crapo Charles Schumer