

**NACDS**

NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

APR 1 2002 APR -1 10:00

April 1, 2002

Margaret Dotzel  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Delay of Effective Date of PDMA Final Rule from April 1, 2002 to April 1, 2003**

Dear Ms. Dotzel:

The National Association of Chain Drug Stores appreciates the opportunity to submit comments on the Food and Drug Administration's delay of the effective date of certain requirements of the Prescription Drug Marketing Act of 1987 (PDMA) final rule to April 1, 2003. NACDS supports two changes to PDMA that would continue to allow secondary wholesalers to operate in the marketplace.

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The goal of PDMA is to ensure that only quality pharmaceutical products are distributed in the United States. These requirements, as written, will cause significant disruption in the secondary pharmaceutical wholesaler marketplace, which has traditionally served as a lower-cost wholesale source of quality pharmaceutical products for pharmacies. Specifically, we support changes to the requirements that relate to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and the burdensome pedigree requirements for secondary wholesalers.

The current regulation would place unreasonable and impractical paperwork and tracking requirements on secondary wholesalers before they could sell the products to retail pharmacies. We do not believe it was the intent of Federal policymakers in enacting PDMA to create burdens for the distribution of quality pharmaceutical products by secondary wholesalers, or to eliminate them from the marketplace.

The extension of the effective date of this regulation provides Congress with the time necessary to consider legislation designed to modify these two wholesale provisions. H.R. 68 and S. 1132, which have been introduced in the House and Senate, respectively, have well over 80 sponsors between them, which is reflective of the serious attention that Congress is directing toward this matter.

Implementation of these regulations would have an adverse impact on potentially thousands of small and medium-sized drug wholesalers across America. NACDS supports the suspension of the implementation of these parts of the final rule.

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We believe that allowing secondary wholesalers to continue to operate under current FDA guidelines, which have been in effect for over a decade, will work well without any harm to the public.

Thank you for the opportunity to express our concerns on this important issue. If you have any questions, please feel free to contact John Coster, Vice President Federal and State Programs at (703) 837-4126.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Lawrence Kocot", written in a cursive style.

S. Lawrence Kocot  
Senior Vice President and General Counsel



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CHAIN DRUG STORES

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