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March 22, 2001

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

**RE: Requirements on Content and Format of Labeling for Human Prescription  
Drugs and Biologicals: Requirements for Prescription Drug Product Labeling  
[Docket No. 00N-1269]**

To Whom it May Concern:

The National Association of Chain Drug Stores (NACDS) commends FDA's proposed changes to the pharmaceutical product packaging label to increase treatment effectiveness and decrease adverse drug events caused by drug-related prescribing errors.

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

NACDS membership consists of nearly 170 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 20,000 traditional chain drug stores, 7,800 supermarket pharmacies and 5,300 mass merchant pharmacies. The NACDS membership base operates over 33,000 retail community pharmacies with annual sales totaling over \$400 billion, including \$160 billion in sales for prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill over 60 percent of 3 billion prescriptions dispensed annually in the United States.

Our organization offers the following comments to assist with the effective implementation of this initiative:

- Compose a list of products affected by the rule (those approved within the last 5 years of the effective date of the proposed rule) and make it available to increase awareness.
- New product labeling requirements to remove "excessive information" should be somehow differentiated in appearance to alert the physician and pharmacist of the changes: (i.e., "New Label Format").

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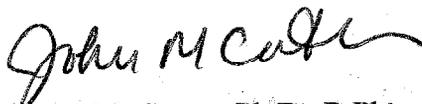
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- New product labeling and inserts for “new/approved use” should be clearly highlighted to enhance prescriber and dispenser awareness.
- Educational messages should be initiated to insure that prescribers and dispensers understand that the ‘highlights’ section is not all-inclusive (from a liability standpoint).

Please contact Deborah Faucette of the NACDS Pharmacy Affairs Department at 703-549-3001 if we can provide any additional information about this issue. Thank you.

Sincerely,



John M. Coster, Ph.D., R.Ph.  
Vice President, Federal and State Programs



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

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