NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 20, 2001

Dockets Management Branch
(HFA-305)
Docket No. OON-1269
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

To Whom It May Concern:

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

The National Association of Chain Drug Stores (NACDS) is pleased to provide additional comments concerning the FDA's proposed changes to the professional product package labeling for all prescription drugs and biologicals. As stated by the FDA, the objective of the proposed change is to make it easier for healthcare practitioners to use and apply the information professional prescription package label.

NACDS membership consists of nearly 180 retail chain community pharmacy companies that operate over 33,000 retail community pharmacies with annual sales totaling over $400 billion. Chain operated community retail pharmacies fill over 60 percent of the approximately 3 billion prescriptions dispensed annually in the United States.

To determine those changes that might make the professional labeling most useful, FDA conducted surveys of physicians. While physicians are an obvious group to survey, NACDS is concerned that the FDA did not include pharmacists in their surveys. Patients rely on their pharmacists for the most current information concerning their prescription medications. For example, a recent on-line informal survey conducted this year by the American Pharmaceutical Association (APhA) found that 59 percent of the pharmacist respondents reference professional labeling at least once daily.

The sections that were most frequently used were the sections on adverse drug reaction, dosage/administration, indications and contra-indications. Pharmacists utilize product labeling the most when the product has been recently introduced into the marketplace, or if they are dispensing the product for the first time.

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Highlights Section

Under the proposed changes, a "highlights" section is to be placed at the beginning of the labeling. Placing this information at the front of the label can help identify the most important product information in a quick and easy way. Caution is warranted, however, that the healthcare provider should not rely solely on the information in this section. NACDS recommends the use of a prominently placed disclaimer within each product label, in addition to the development of an educational program for users, that emphasizes the role and the limitations of the highlights section.

Indexing

The use of a standardized indexing system, which can be consistently applied to all drug products, is beneficial. This will allow for familiarity and easy searchability of the professional labeling. Boxed warnings should be noted with an icon (explanation point) at the very beginning of the prescribing information in order to maintain the integrity of the index. Additionally, the boxed warning should be included within the highlights section.

Recent Labeling Changes

The one-year duration for listing of recent labeling changes is sufficient. However, NACDS recommends that the actual date of each specific label change be noted immediately following the label change.

Standardized Headings in Warning/Precautions

NACDS recommends the use of a standardized heading when appropriate, making the information easily accessible for the healthcare provider. NACDS also recognizes that this may be difficult to manage due to the diversity of the information among various drug products, and therefore recommends that the FDA allow manufacturers some flexibility in reporting the data.

Adverse Drug Reactions Reporting

NACDS supports a listing of contact numbers for adverse drug reaction reporting in the highlights and comprehensive prescribing information sections. Making this information readily available through the package insert will hopefully encourage increased use of this resource by healthcare providers.

Font Size

NACDS recommends the use of 10-point font or larger for professional package labeling. This size will enhance readability, especially if the product labeling is provided to patients, specifically seniors.

Patient Counseling Information

NACDS supports the inclusion of a separate section at the end of the product labeling with patient counseling information. Pharmacists and other healthcare providers can readily access this information. NACDS agrees that if a "MedGuide" should have to be included with the product labeling, then it should be placed after the patient counseling section of the label.

Electronic Distribution of the Label

NACDS is concerned that FDA might use this proposed revision of the product labeling to make changes in the current labeling distribution requirements to professionals. That is, we understand that manufacturers are advocating that the professional labeling be distributed in electronic format only.

NACDS would like to caution the FDA that the technology does not exist at this point in time for this type of change to be made. Of the over 70,000 dispensing sites in the United States, only about 18-20 percent have Internet access. While in general this number is steadily increasing, there are still many pharmacies and physician offices operating without internet access. In addition, the technological infrastructure, including hardware and software requirements to move to an electronic label, vary considerably depending upon the location.

While NACDS may agree that the eventual elimination of paper labels in the workplace can have merit, we feel strongly that a change in the regulation is inadvisable at this juncture, as well as impractical. NACDS would welcome further discussion on this topic if so desired.

Educational Program

Lastly, NACDS recommends that the FDA develop a comprehensive educational outreach program when the new regulations are implemented. This will not only increase awareness, but also assure a seamless transition with healthcare providers. It will be imperative that all users understand the format of the new label and be familiar with its contents. In addition, a published list of products with requirement dates for new labeling should be available.

On behalf of chain community pharmacy, NACDS appreciates the opportunity to submit comments on this very important proposed change in regulations. If questions arise or a need for further clarification occurs, please contact Edith Rosato, R.Ph., Vice President, Pharmacy Affairs at (703) 549-3001, ext. 186 or erosato@nacds.org.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel

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