



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

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May 25, 2007

Food and Drug Administration
Docket No. 1977N-0094L
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Subject: Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling - RIN 0910AF36

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) is writing to comment on the proposed rule referenced above. NACDS represent companies that operate more than 37,000 community retail pharmacies in the United States. Our members are a primary source of sales of Over-the-Counter (OTC) medications, including those containing acetaminophen (APAP), aspirin (ASA) and other non-steroidal anti-inflammatory drugs (NSAIDs).

In general, NACDS supports the proposed labeling and warning changes. We understand that many consumers take both prescription and OTC drugs, and may be unaware that there are similar ingredients in many products. We also know that many consumers may take multiple OTC products that have similar ingredients. Our comments are as follows:

- We support the inclusion of the phrase "*Ask your doctor or pharmacist before using with other drugs if you are not sure*" on the label of OTC medications containing APAP and NSAIDs. Pharmacists are a primary source of information for consumers about prescription and OTC medications, and can often help consumers determine if there are duplicate ingredients in any of the prescription medications that they may be taking.
- We believe that the inclusion on the label of the OTC product of the term "Acetaminophen" or the identity of the NSAID along with the term "NSAID" would be helpful to consumers in understanding that these products contain these ingredients. This could be helpful in avoiding overdoses of these medications. We question, however, whether consumers will know why these terms are now prominently being displayed on the Principal Display Panel (PDP). Would a consumer know what "acetaminophen" is used for, or what an "NSAID" is used for, or would they think that is the only active ingredient in the product?

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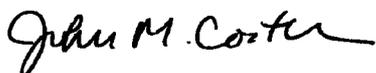
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Many consumers are educated on the purposes of particular ingredients in OTC medications, but some may not know why the terms are listed prominently on the PDP, or their medical purposes, such as pain. The FDA may want to require that the terms "contains Acetaminophen" or "contains (name of NSAID), a pain medication" be used rather than just "acetaminophen" or "NSAID". Moreover, we believe that these label changes should be accompanied by some type of informational campaign that will help consumers understand why these labeling changes were made. For example, there will most likely be confusion surrounding the fact that "acetaminophen" is an active product ingredient whereas "NSAID" is a category of products.

- NACDS is concerned that the PDP not become too overcrowded with information such that the consumer has difficulty in distinguishing among various types of OTC products or particular brands of various OTC products. Labels tend to already be too crowded, and we are concerned that manufacturers may have to increase the size of the package to accommodate these changes. That could have significant economic impacts on the OTC business, and may increase the amount of shelf space needed for each product.
- As is the case with any prescription or non prescription product, there are benefits as well as risks to taking these products. NACDS is concerned that these additional "warnings", while attempting to inform consumers about possible risks, could result in consumers not taking these medications because of the significant emphasis on risk information.

We appreciate the opportunity to submit comments on this important issue. Please contact us for further information at 703-837-4126. Thank you.

Sincerely,



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