

77n-0094L-ereg0001.txt

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Public Comments on 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: =====

Title: 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
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This is a response to a call for comment for Docket No. 1977N-0094L, written by the University of Virginia RN-BSN students listed above.

First, we would like to thank you for taking the time to bring light to this important issue. As registered nurses, we see the consequences of inadequate consumer awareness about health care issues on a daily basis. We fully support the FDA's proposal to incorporate changes in the warning labels of over the counter medications to ensure the safety of the public at large.

The FDA proposal to incorporate new warning labels for OTC medications would greatly increase consumer education and awareness. These labels are essential to protect the patients and to make them more informed consumers. The new labels will likely decrease accidental overdoses and increase patient's confidence in their ability to manage their medical conditions effectively. The proposed changes are especially important for products containing acetaminophen, aspirin, or other non-steroidal anti-inflammatory drugs (NSAIDs).

The new labels are significant for medications that contain acetaminophen due to the increased likelihood of liver toxicity when the dose exceeds 4 grams per day. Many individuals are unaware that acetaminophen can be toxic to the liver, and the new warning labels will be particularly valuable to those with

pre-existing liver conditions such as cirrhosis, Hepatitis B, and Hepatitis C. The labels should also include the fact that the drug should not be taken with alcohol, as this will increase the likelihood hepatotoxicity. All medication that contains acetaminophen should be clearly labeled in this manner.

New medication labels are also essential for medications that contain aspirin or other NSAIDs. Many medications that include aspirin or NSAIDs are not labeled clearly. This can be very dangerous for consumers who have renal insufficiency, renal failure, gastrointestinal bleeding, or thrombocytopenia. These drugs can also be dangerous for patients taking medications such as coumadin, heparin, or other anticoagulants. Therefore, these and other similar medications should clearly state that aspirin or NSAIDs are a part of the drug combination. Furthermore, these individuals may not realize that aspirin and other NSAIDs may increase bleeding tendencies or further impair renal function. We support the proposal that even medications such as aspirin and ibuprofen should have clear warning labels stating that they should not be taken by individuals with renal insufficiency, individuals taking coumadin or other anticoagulants, or patients with bleeding tendencies.

Another reason we support this proposal is that we believe it will prevent unnecessary hospitalizations related to inappropriate usage of the medications. Many consumers are unaware that acetaminophen is a common ingredient in both over the counter remedies as well as prescription medication. Unintentional overdose of acetaminophen can lead to acute liver failure, with approximately 1,000-2,000 cases reported each year. In a study conducted by Dr. William Lee of University of Texas Southwestern Medical Center at Dallas, over 50% of acute liver failure was caused by accidental overdose of acetaminophen. Much suffering could have been spared if the public had been more informed about the medications they were taking.

Treating unintentional acetaminophen overdose cases can be costly, resulting in emergency room visits and hospital admissions that could have been avoided. At least 100 deaths from accidental overdose were reported between 1996 and 1998. For those who survive the initial overdose, the resulting liver disease can be devastating, as over 1,300 people died in 2001 while waiting for a transplant. Inadequate packaging and insufficient consumer awareness have contributed to these tragic numbers, and this proposal is a necessary action.

The new requirements for the labels take the lay person's knowledge into account. The drug name (i.e. Acetaminophen) must be highlighted or set in a different background color. Consumers that have little to no medical experience will become exposed more to the drug names and have a stronger awareness. Also, the labels must now list systemic effects in a specific order. Liver damage is first in line to be listed? this is very important as people take this warning lightly only to find themselves seriously ill or with permanent liver damage. Instructions to speak with a physician before taking the medication if the consumer has ever had liver disease should be included. The label will also feature a warning about possible interaction between the medication and excessive alcohol intake. Most of the general population is unaware that over the counter drugs and alcohol make the liver work much harder and can cause serious damage. By grouping these issues together on the warning label, it will create a connection for the average consumer.

As health care providers and regulators, it can be easy to forget that not everyone understands basic physiologic interactions. Changing over the counter medication labeling regulations will increase public awareness and how these products are consumed. As nurses, we feel that this is a very important step in the right direction toward safer and more informed consumers. This regulation will enhance patient autonomy and will provide for fewer accidental overdoses. Therefore, this regulation will benefit the American public at large.

Sincerely,

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