



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

5782 '03 SEP -2 P1:40
SEP 02 2003

RE: Internal Analgesic, Antipyretic and Antirheumatic
Drug Products for Over-The-Counter Human Use;
Proposed Amendment of the Tentative Final
Monograph and Related Labeling [Docket No. 77N-0941]

Dear Sir/Madam:

McNeil Consumer & Specialty Pharmaceuticals is submitting these comments in response to the June 4, 2003 *Federal Register* announcement which re-opened the docket to accept comments on the Agency's proposed rule to amend the Tentative Final Monograph (TFM) for over-the-counter internal analgesic, antipyretic and antirheumatic (IAAA) drug products to include ibuprofen as a generally recognized safe and effective analgesic/antipyretic active ingredient for OTC use.

On September 20, 2002, FDA held a meeting of the Nonprescription Drugs Advisory Committee (NDAC) to discuss safety issues related to the use of aspirin and other OTC nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen. The Agency asked the NDAC to consider if additional warnings or other risk management strategies were needed to alert consumers with regard to potential gastrointestinal (GI) bleeding and renal insufficiency related to OTC use of these drug products. During the meeting, there were discussions about the need for adding a separate warning statement for stomach bleeding and one for concomitant use of multiple NSAID products. The committee also raised the issue of a continuing need for an alcohol warning on ibuprofen if a stomach bleeding warning was adopted.

Subsequent to the NDAC, one manufacturer, Wyeth Consumer Healthcare, submitted comments to the docket to support their position that the current alcohol warning for ibuprofen products is not warranted and should be removed from OTC ibuprofen labeling. This submission addresses McNeil's perspective about the continuing need to include an alcohol warning on all OTC internal analgesic/antipyretic drug products, including ibuprofen, and also responds to NDAC discussions of September 20, 2002.

McNeil has prepared a separate submission to the docket which addresses our comments on adding ibuprofen 200mg tablets to the Internal Analgesic monograph and our comments on FDA's proposed labeling changes for OTC ibuprofen and other OTC NSAID internal analgesic drug products covered under the TFM.

If you have any comments or require additional information on this submission, please contact me at 215-273-7878.

Very truly yours,

Paula J. Oliver
Senior Director, Regulatory Affairs

Attachment

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