

Wyeth Consumer Healthcare
Five Giralda Farms
Madison, NJ 07940

Sharon C. Heddish
Vice President,
Global Regulatory Affairs

973-660-5753 tel
heddiss@wyeth.com

Wyeth

October 11, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. 77N-0941
Internal Analgesic, Antipyretic, and Antirheumatic Drug Products
for Over-the-Counter Human Use; Proposed Amendment of the
Tentative Final Monograph (TFM), and Related Labeling
(FR Vol. 67, No. 162 dated August 21, 2002)**

To Whom It May Concern:

Wyeth Consumer Healthcare ("Wyeth"), requests that an extension of ninety (90) days be granted for submission of comments on the proposed rule to include ibuprofen in the TFM.

The meeting notice for the September 19-20, 2002 Nonprescription Drug Advisory Committee (NDAC) was published on August 20, 2002, one day before the subject proposed rule was published. In this notice, FDA indicated its intention to consider ways to improve labeling for all OTC internal analgesics, including ibuprofen. In anticipation of having this topic brought before the NDAC, Wyeth began work that would be the basis of a response to the TFM. However, Wyeth delayed completion of the work and the response, so that consideration could be given to the impact of the NDAC discussions on product labeling. Therefore, Wyeth requires additional time to evaluate and comment on labeling suggestions that arose from the NDAC.

Wyeth will use this time to review the pre-clinical and clinical safety data that the Agency has used to support the inclusion of specific label warning statements. More importantly, Wyeth may also conduct consumer research that

77N-0941

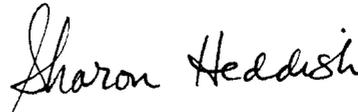
EXT 1

Wyeth

could provide information relevant to the crafting of a label which achieves the intended communication goal and further maximizes safe and appropriate use.

Wyeth Consumer Healthcare appreciates the opportunity to submit comments to the proposed rule. Careful consideration of all available information must be given to assure the development of the best possible label for OTC internal analgesic products containing ibuprofen. Accordingly, Wyeth requests that the FDA grant our request for an extension of ninety (90) days to the comment deadline.

Sincerely,
WYETH CONSUMER HEALTHCARE



Sharon C. Heddish
Vice President, Global Regulatory Affairs

Cc: Charles Ganley, M.D. (HFD-560)