

Bayer HealthCare
Consumer Care Division

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May 24, 2007

Leonard M. Baum, RPh
Vice President
Global Regulatory Affairs

Submitted by Fax

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 1977N-0094L/RIN 0910-AF36
Internal Analgesic, Antipyretic, and Antirheumatic Drug
Products for Over-the-Counter Human Use; Proposed
Amendment of the Tentative Final Monograph; Required
Human Use; Proposed Amendment of the Tentative Final
Monograph; Required Warnings and Other Labeling,
71 Fed. Reg. 77314-52 (December 26, 2006)

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Dear Sir or Madam:

In the December 26, 2006, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced proposed rule, which proposes new warning and other labeling requirements for internal analgesic, antipyretic, and antirheumatic over-the counter (OTC) drug products.

Bayer HealthCare (Bayer) supports the Agency's goals to further improve the safe and effective use of internal analgesic, antipyretic and antirheumatic products by prescribers, patients and consumers. Bayer is submitting comments herein to the proposed rule.

In the April 6, 2005 memorandum from Drs. Jenkins and Seligman on "Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk", the FDA notes that...

"Aspirin is also an NSAID that is available and widely used without a prescription. However, aspirin has other unique pharmacologic properties, including irreversible inhibition of platelet function, that distinguish it from the rest of the NSAID class. Further, data from long-term controlled clinical trials have clearly demonstrated that aspirin significantly reduces the risk of serious adverse CV events in certain patient populations (e.g., patients with a history of a MI). Aspirin, therefore, is an exception to the apparent 'class effect' of increased risk for serious adverse CV events for NSAIDs described above."

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The April 6, 2005 memorandum also notes that.....

"To further encourage the safe use of the non-prescription NSAIDs, we (the Agency) believe that the labeling for these products should be revised to include more specific information about the potential CV and GI risks, instructions about which patients should seek the advice of a physician before using these drugs, and stronger reminders about limiting the dose and duration of treatment in accordance with the package instructions unless otherwise advised by a physician."

While data from long term trials clearly exempts aspirin from the CV risk statement being proposed in the December 26, 2006 FR for the NSAID's as a class, the Agency has proposed placing "NSAID" prominently on the PDP and in Drug Facts labeling "so consumers are aware of the presence of the ingredient in the product".

However, while aspirin is exempt from the NSAID CV risk warning, the Agency has proposed a number of other label warning statements that apply to the NSAIDs as a class (i.e. GI). This has already created confusion for the consumer and in the media as has been our experience in 2005, when the Agency initiated the safety statements for the NDA prescription and non-prescription NSAID's, including the COX-2 agents.

We believe at a minimum that the Agency should exempt aspirin from the requirement for placing "NSAID" on the PDP. To further reduce the potential confusion and clearly identify that the NSAID-aspirin is exempt from the CV risk statement, Bayer is requesting that the statement that has been underlined below, be included as part of the "Uses" section of the OTC labeling.

Uses

- Temporarily relieves
 - o Headache
 - o Menstrual pain
 - o Minor pain of arthritis
 - o Muscle pain
 - o Toothache
 - o Pain and fever of colds
- As directed by a doctor for prevention of heart attack and stroke

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Bayer believes this statement will provide useful information to the consumer by acknowledging that the NSAID – aspirin does not have a CV risk while still maintaining the current aspirin professional labeling and need for a consumer to talk to their doctor.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "L. M. Baum".

Leonard M. Baum, RPh

Cc: Charles Ganley, MD