



2 REGULATORY HISTORY

On August 21, 2002, a proposed rule was published in the *Federal Register* to amend the Tentative Final Monograph (TFM) to include ibuprofen tablets 200 mg as a generally recognized safe and effective internal analgesic/antipyretic active ingredient for adult OTC use. In addition, the proposed rule included amendments to the regulations to include consistent allergy warnings for OTC internal analgesic products containing NSAIDs.

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. FDA asked the NDAC to consider if additional warnings or other risk management strategies were needed to alert the consumer with regard to potential gastrointestinal (GI) bleeding and renal insufficiency related to the OTC use of these drug products. At this meeting, the NDAC members also discussed other OTC NSAID labeling topics that were not included in FDA's Proposed Rule of August 21, 2002. However, FDA indicated that discussions at the meeting might be considered as comments to the Proposed Rule.

On June 4, 2003, the comment period on the August 21, 2002 proposed rule to amend the TFM was reopened via a *Federal Register* announcement [68 FR 33429] to provide additional time to fully evaluate the impact of NDAC discussions of OTC IAAA drug products, including ibuprofen, at its September 20, 2002 meeting and to evaluate the proposed additions of August 21, 2002 to the TFM.