



4 CONCLUSIONS

- McNeil agrees with FDA's proposal that ibuprofen 200 mg tablets be generally recognized as safe and effective as an OTC IAAA drug for adults and children 12 years of age and older.
- McNeil recommends extending OTC monograph status to other single ingredient ibuprofen 200 mg dosage forms labeled for adult use. McNeil believes that there is sufficient safety experience with the nonprescription use of the active ingredient, ibuprofen, to support extending OTC monograph inclusion to all single ingredient ibuprofen 200 mg dosage forms labeled for adult use, regardless of dosage form.
- McNeil concurs with FDA's belief that ibuprofen adult dosage forms, if labeled with appropriate warnings and directions for use, can be marketed OTC under the monograph system for the indications previously approved under the NDA/ANDA process.
- McNeil can support the Agency's view that, for consistency, the "Allergy alert" and additional allergy warning statements stated in FDA's Proposed Rule should be standardized and extended to all OTC NSAID IAAA drug products, whether marketed under an OTC drug monograph or an NDA/ANDA.

- McNeil believes that the current labeling for OTC ibuprofen products, including the alcohol warning, is appropriate for safe consumer use. We also recognize that FDA has been implementing OTC labeling modifications that provide more specific language related to organ systems, disease states, and symptoms. As such, McNeil is committed to adopting the specific format and language of warnings proposed by FDA provided that the warnings have a sound scientific basis.

- In this regard, McNeil can support FDA's proposed new label warning statements for OTC ibuprofen related to gastrointestinal effects, renal effects and use of anticoagulant drugs.