



1 INTRODUCTION

McNeil Consumer & Specialty Pharmaceuticals (McNeil), a major manufacturer of over-the-counter (OTC) internal analgesic drug products, markets a comprehensive line of Motrin (ibuprofen) brand single-ingredient and combination-ingredient products for adults, children, and infants. McNeil also markets St. Joseph low strength (81 mg) aspirin for use by adults only, as well as Tylenol (acetaminophen) single-ingredient and combination-ingredient products for adults, children and infants. As a major manufacturer of these products, McNeil is committed to encouraging scientifically appropriate and adequate labeling for all active ingredients in the internal analgesic/antipyretic category of OTC drugs, which includes consistent and clear language for consumer use.

In response to FDA's request for comments on a proposed rule to amend the Tentative Final Monograph (TFM) for internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include ibuprofen tablets 200 mg as a generally recognized safe and effective internal analgesic/antipyretic for adult OTC use, this submission provides McNeil's perspective on the Agency's proposals.