

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.

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. In the following sections, McNeil provides comments on NDAC discussions during the September 20, 2002 meeting and responses to comments filed to Docket No. 77N-0941 subsequent to this meeting.