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Section I

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Nonprescription Drugs Advisory Committee Meeting
September 19 & 20, 2002
Hilton - Maryland Ballroom - Silver Spring, MD

September 19, 2002 - the committee will discuss safety issues related to the use of acetaminophen. The primary area for discussion will focus on potential hepatotoxicity related to the use of acetaminophen in both OTC and prescription (RX) products.

September 20, 2002 - the committee will discuss safety issues related to the use of aspirin and other over-the-counter non-steroidal anti-inflammatory drugs (NSAIDS). The primary areas for discussion will focus on potential gastrointestinal bleeding and renal insufficiency related to the use of these products.

In rulemaking, the agency has proposed aspirin and acetaminophen as Category 1 ingredients for safety and effectiveness. Other NSAIDS and combination products are marketed under new drug applications. The agency continues to believe that these ingredients are safe and effective for OTC use. The advisory committee will discuss whether labeling or other measures are warranted to seduce the risk if occurrence or the severity of these adverse reactions.

SECTION I:
OVERVIEW and FEDERAL REGISTER DOCUMENTS

A	**Overview of the September 19 and 20, 2002 NDAC Meeting**
B	**Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Antirheumatic Products (Panel Report or ANPR)** *[Entire Federal Register Notice Is Not Included]*
C	**Internal Analgesic, Antipyretic and Antirheumatic Products for Over-The-Counter Human Use; Tentative Final Monograph** *[Entire Federal Register Notice Is Not Included]*
D	**Over-The-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning (Notice of proposed rulemaking)**
E.	**Over-The-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning (Final Rule)**
F.	**Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the - Counter Human Use; Final Rule for Professional Labeling of Aspirin, Buffered Aspirin, and Aspirin in Combination with Antacid Drug Products**
G.	**Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the - Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling**

SECTION II: ACETOMINOPHEN REVIEWS

	TOPIC	REVIEWER
A.	Archeological Review of the Regulatory History of OTC Single Ingredient Acetaminophen	Neuner
B.	Acetaminophen- PK/Metabolism	Bashaw/Abebowale
C.	Acetaminophen -Containing Products-Hepatotoxicity	Karwoski
D.	Acetaminophen – Utilization Data	Nourjah
E.	Acetaminophen –Epidemiology of Acetaminophen-related overdose - National Mortality Data	Nourjah
F.	Review of Acetaminophen Poisoning Exposures in Toxic Exposure Surveillance System (TESS)	Ahmad
G.	Review of Adult and Adolescents Exposure Data on Acetaminophen-containing Products from Two Regional Poison Control Centers	Ahmad
H.	Acetaminophen Overdose Reference Articles	
	Emerging Trends in Acute Liver Failure in U.S. - Abstract	Lee

SECTION III: NSAID/ASPIRIN REVIEWS

	TOPIC	REVIEWER
A.	Literature Search Submitted in Preparation for the September 2002 NDAC Meeting	Neuner
B.	NSAID Renal Review	Johnston
C.	Renal Toxicity References (6)	
D.	Aspirin -GI Bleed	Karwoski
E.	NSAID-GI Bleed	Bonnel/Weaver
F.	NSAID/ASA GI Bleed References (5)	