

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)***

Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
April 4, 2017

QUESTIONS

1. **DISCUSS:** Discuss the safety of the use of over-the-counter (OTC) analgesic combination products for the relief of minor aches and pains associated with heartburn, sour stomach, acid indigestion, fullness, belching, gas, or nausea.
2. **VOTE:** Is the combination of an analgesic with antacids a rational combination for OTC use for the relief of minor aches and pains associated with heartburn, sour stomach, acid indigestion, fullness, belching, gas, or nausea?
3. Hangover is defined in the monograph as a condition consisting of a complex of symptoms involving the gastrointestinal, neurologic, and metabolic system that follows recent acute and excessive alcohol ingestion. The monograph states that the symptoms may include nausea, heartburn, thirst, tremor, disturbances of equilibrium, fatigue, generalized aches and pains, headache, dullness, and/or depression or irritability.

DISCUSS: Discuss whether or not the treatment of hangover is an appropriate indication for OTC drug products. If the hangover indication is appropriate, which ingredients would be options for the treatment of the symptoms?

We are particularly interested in a discussion of aspirin or acetaminophen as acceptable ingredients to include in combination products for the treatment of hangover. Consider in your discussion the indications for hangover in the monograph, the association of alcohol and NSAIDs with gastrointestinal bleeding, the association of alcohol and acetaminophen with liver toxicity, and the safety information presented in this meeting.