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

AGENDA

The committees will discuss safety issues associated with over-the-counter analgesic combination products used for upset stomach (i.e., heartburn, nausea, fullness, belching, gas, acid indigestion, and/or sour stomach) and hangover indications under the Internal Analgesic and Antacid monographs in 21 CFR part 343 and 21 CFR part 331, respectively. The committees will also be asked to discuss the hangover indication under the Overindulgence, Internal Analgesic, and Stimulant monographs in 21 CFR part 357 subpart J, 21 CFR part 343, and 21 CFR part 340, respectively.

8:00 a.m.	Call to Order and Introduction of Committee	**Christianne L. Roumie, MD, MPH** Chairperson, NDAC
8:05 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, NDAC
8:10 a.m.	FDA Introductory Remarks	**Valerie Pratt, MD** Deputy Director for Safety Division of Nonprescription Drug Products (DNDP) Office of Drug Evaluation IV (ODE IV) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**FDA PRESENTATION**	
	Analgesic Combinations in the Over-the-Counter (OTC) Monographs	**Captain Mary Vienna, USPHS, Ret.** Interdisciplinary Scientist Reviewer DNDP, ODE IV, OND, CDER, FDA
8:50 a.m.	**INDUSTRY PRESENTATIONS**	
	Introductory Remarks	**Barbara Kochanowski, PhD** Consumer Healthcare Products Association (CHPA)
	Alka-Seltzer Aspirin/Antacid Combination Products	**Andre Schmidt, MD** Bayer HealthCare LLC
	Introduction to Hangover	**Jay Sirois, PhD** CHPA
	Clinical Investigation of Hangover	**Damaris Rohsenow, PhD** Brown University (Consultant to CHPA)

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AGENDA (cont.)

	INDUSTRY PRESENTATIONS (CONT.)	
	OTC Products for Hangover Under the FDA Monograph	**Brenna Haysom** Rally Labs LLC
	Summary	**Barbara Kochanowski, PhD**
10:20 a.m.	Clarifying Questions	
10:35 a.m.	**BREAK**	
10:50 a.m.	**FDA PRESENTATIONS**	
	Postmarketing Safety Data	**Ali Niak, MD** Medical Officer Division of Pharmacovigilance I Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology CDER, FDA
	Selected Clinical Literature Overview	**Ketan Parikh, MD** Medical Officer DNDP, ODE IV, OND, CDER, FDA
11:50 a.m.	Clarifying Questions	
12:05 p.m.	**LUNCH**	
1:05 p.m.	Open Public Hearing	
2:05 p.m.	Charge to the Committee	**Valerie Pratt, MD**
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	