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

Nonprescription Drugs Advisory Committee (NDAC) Meeting
Hilton Washington DC North/Gaithersburg, The Ballrooms
620 Perry Pkwy., Gaithersburg, Maryland
April 15, 2016

DRAFT AGENDA

The committee will discuss data submitted by Galderma Laboratories, L.P. to support supplemental new drug application (sNDA) 20-380, for over-the-counter (OTC) marketing of adapalene gel 0.1%. The proposed OTC use is for the treatment of acne and to clear up acne pimples and acne blemishes. The applicant proposes to label the product for 12 years and older. The committee will be asked to consider whether data support an acceptable risk/benefit profile for the nonprescription use of adapalene gel 0.1% by OTC consumers.

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	**Theresa Michele, MD** Director Division of Nonprescription Drug Products (DNDP) Office of Drug Evaluation IV (ODE IV) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**Galderma Laboratories, L.P.**
	Introduction	**Howard Marsh, MD** Vice President of Medical Affairs, Galderma
	Dermatologist Perspective	**Guy Webster, MD, PhD, FAAD** Webster Dermatology and Professor of Clinical Dermatology Jefferson College, Philadelphia
	Efficacy and Safety	**Matthew Meckfessel, PhD** Medical Lead, Self-Medication, Galderma
	Toxicology	**John DeSesso, PhD, DABFM, DABFE, FACFEI, DABCHS, Fellow ATS** Director, Center for Toxicology and Mechanistic Biology, Exponent Professor of Biochemistry, Molecular & Cellular Biology Georgetown University School of Medicine
	Consumer Studies	**Julie Aker, MT (ASCP)** President and CEO, Concentrics Research

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APPLICANT PRESENTATIONS (CONT.)

	Benefit-Risk Assessment	**Jonathan Wilkin, MD** Director of Dermatology at Ohio State University (Retired) Founding Director of FDA Division of Dermatology & Dental Products (Retired)
	Conclusion	**Howard Marsh, MD**
9:50 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Maximal Usage Trial (MUsT) Data	**Chinmay Shukla, PhD** Clinical Pharmacologist Division of Clinical Pharmacology III Office of Clinical Pharmacology Office of Translational Sciences , CDER, FDA
	Nonclinical Summary	**Cindy Li, PhD** Toxicologist DNDP, ODE IV, OND, CDER, FDA
	Label Comprehension and Self-Selection Studies	**Barbara Cohen, MPA** Social Science Analyst DNDP, ODE IV, OND, CDER, FDA
	Actual Use Trial & Clinical Perspective	**Ryan Raffaelli, MD** Medical Officer DNDP, ODEIV, OND, CDER, FDA
	Postmarketing Prescription Safety Data	**Lopa Thambi, PharmD** Safety Evaluator Division of Pharmacovigilance II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology CDER, FDA
	Benefit: Risk Profile	**Jane Filie, MD** Lead Medical Officer DNDP, ODE IV, OND, CDER, FDA

11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Valerie Pratt, MD** Deputy Director for Safety DNDP, ODE IV, OND, CDER, FDA
2:10 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**	