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

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
Christiane 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 (DNBP)
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
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