

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	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, FAFCEI, 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

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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**