

Orphan Drug Designation workshop

February 25-26, 2010

Keck Graduate Institute

535 Watson Drive, Claremont, California



WORKSHOP SCHEDULE

Thursday, February 25, 2010-Founders Room

8:00-8:50 am Breakfast
8:50-9:00 am Welcome
Sheldon Schuster, President, KGI

Session I

9:00-10:00 am Introduction to the Workshop
Tim Coté, MD, MPH
Director, OOPD, FDA

Session II

10:00 am - Noon Participants work in small groups for one-on-one guidance and counseling with FDA staff

Noon-1:30 pm Lunch -Alumni Patio

Session III

1:30-5:30 pm Independent work on application. FDA staff provide guidance and answer questions.

5:30 pm Break

6:00-7:00 pm Reception-Founders Room

7:00 pm Dinner on your own

Friday, February 26, 2010-Founders Room

8:00-8:30 am Breakfast

Session IV

8:30 am - Noon Continuation of application writing

Noon -1:30 pm Lunch -Alumni Patio

1:30-4:00 pm Independent writing

4:00-5:00 pm Wrap-up

5:00 pm End of Workshop

Applications submitted to FDA onsite

NOTE: All sessions are in Bldg 517 unless otherwise indicated

Hotels in Claremont

Doubletree Claremont
555 West Foothill Blvd.
Claremont, CA 91711
(800) 222-8733
www.doubletree.com

Casa 425
425 West First Street
Claremont, CA 91711
(866) 450-0425
www.casa425.com

Airports near Claremont

Ontario International (ONT) 9 miles away

John Wayne Orange County (SNA) 37 miles away

Bob Hope Burbank (BUR) 42 miles away

Los Angeles International (LAX) 51 miles away

Directions to KGI can be found at:

www.kgi.edu/x1890.xml

SPONSORS



KECK GRADUATE INSTITUTE
of Applied Life Sciences



For More Information

Laura Sturr, Administrator, KGI Center for Rare Disease Therapies

(909) 607-0120 or Laura_Sturr@kgi.edu