Carolyne R. Hathaway
Direct Dial: (202) 637-2279
carolyne.hathaway@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: (202) 637-2200 Fax: (202) 637-2201
www.lw.com

LATHAM & WATKINS LLP

FIRM / AFFILIATE OFFICES

Barcelona	New Jersey
Brussels	New York
Chicago	Northern Virginia
Frankfurt	Orange County
Hamburg	Paris
Hong Kong	San Diego
London	San Francisco
Los Angeles	Shanghai
Madrid	Silicon Valley
Milan	Singapore
Moscow	Tokyo
Munich	Washington, D.C.

April 3, 2007

BY FACSIMILE AND FEDERAL EXPRESS

Gary J. Buehler
Director
Office of Generic Drugs, HFD-600
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

Re: ANDA 78-453/*Mylan Laboratories, Inc. v. Leavitt, CA No. 07-579 (D.D.C.)*

Dear Dr. Buehler:

We write on behalf of Orchid Healthcare (Orchid), in response to your letter dated March 28, 2007 to Orgenus Pharma, Inc., Orchid's U.S. Agent. Your letter solicits Orchid's comments on certain questions relating to the above-referenced litigation, regarding Abbreviated New Drug Applications (ANDAs) for generic amlodipine besylate tablets. As Orchid has filed a paragraph III certification in its ANDA for generic amlodipine besylate tablets (ANDA 78-453), Orchid does not have any specific comments regarding the issues presented by the Agency's questions. Orchid appreciates the opportunity to provide comments on the important legal and policy issues raised by the questions in your letter, and defers to the Agency's interpretation of applicable law and its regulations in reaching a resolution of the issues presented.

Thank you for this opportunity to provide comments on the issues related to ANDAs for amlodipine besylate tablets raised in your letter. Please do not hesitate to contact me at (202) 637-2279 if you have any questions or wish to discuss this matter further.

Respectfully submitted,

C. Hathaway

Carolyne R. Hathaway
of LATHAM & WATKINS LLP

cc: Satish Srinivasan
Orgenus Pharma, Inc.