HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 15 2006

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Brian S. Roman, Esq.
Vice President and General Counsel
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, West Virginia 26504-4310

Re: Docket No. 2006P-0245/CP1

Dear Mr. Roman:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 13, 2006. Your petition requests that the Agency award Mylan Pharmaceuticals Inc. (Mylan) 180-day marketing exclusivity with respect to its abbreviated new drug application (ANDA) for risperidone tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg. You contend that, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, FDA should base exclusivity determinations on the date notice was given by an ANDA applicant of its Paragraph IV certification, not the date the certification was filed with FDA.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0245

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