



MYLAN PHARMACEUTICALS INC

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June 15, 2006

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VIA FACSIMILE: (301) 827-6870

Jennie Butler
Dockets Supervisor
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20857

RE: Docket #2006P-0245
Exclusivity Determination for Risperidone

Dear Ms. Butler:

On behalf of Mylan Pharmaceuticals Inc. ("Mylan"), please find below the Environmental and Economic impact statements for the above-referenced citizen petition:

ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exemption from environmental assessment under 21 C.F.R. §§ 25.22 and 25.31.

ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30(b), Mylan will provide data concerning the economic impact of the relief requested should such information be requested by FDA.

Sincerely,

Brian S. Roman
V.P. and General Counsel
Mylan Pharmaceuticals Inc.

Department—Fax Numbers

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