



MYLAN PHARMACEUTICALS INC

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6003 '04 FEB -3 1943

February 2, 2004

VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket Number 2003P-0366

Dear Sir/Madam:

Mylan Pharmaceuticals Inc. ("Mylan") submits this Supplement to its December 11, 2003 Comment in support of the Citizen Petition dated August 12, 2003. The topic of the Citizen Petition is Prilosec OTC (omeprazole magnesium).

Mylan's December 11, 2003 Comment provided a number of examples relative to the marketing and use of Prilosec OTC. In addition, issues were raised regarding the fact that Prilosec OTC is being permitted to be marketed as interchangeable with Prilosec Rx simply because they share the same name. Furthermore, Mylan submitted its bioequivalency study which concluded that the Rx and OTC forms are not bioequivalent. This Supplement provides additional evidence to that important point.

The Procter & Gamble Company has conceded this fact by stating it **"...admits that Prilosec OTC is not bioequivalent to the Prilosec Rx sold in the United States** and avers that any absence of bioequivalence is therapeutically irrelevant"¹ The impact of this extends not only to the FDA's review of the issues previously raised under the above-captioned docket, but also to the reality of the marketplace with respect to the unrestricted interchangeability and substitution of Prilosec OTC for Prilosec Rx.

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¹ See *Mylan Pharmaceuticals Inc. against The Procter & Gamble Company* filed in the United States District Court, Southern District of New York, Case No.: 03 Civ. 10150 (HB).

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Sincerely,


Stuart A. Williams
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SAW/kaa

cc: w/encl. Janet Woodcock, MD, Center Director
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