



The Procter & Gamble Company

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March 29, 2004

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-O366 ("Mattingly Petition")

Dear Sir or Madam:

We received a copy of Mylan Pharmaceuticals' February 2, 2004 letter regarding the above docket. Mylan's letter cites a statement from a Procter & Gamble court filing to the effect that Prilosec OTC and Rx Prilosec capsules are not bioequivalent. The letter states that "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 market place with respect to the unrestricted interchangeability and substitution of Prilosec OTC for Prilosec Rx."

In fact, the statement has no impact, as it does not represent any information new to the Agency. As the FDA's medical reviewer stated in the public briefing materials for the October 20, 2000 advisory committee on the Prilosec Rx-to-OTC switch:

"Results of bridging studies to compare OME-Mg and Omeprazole indicate that their toxicokinetic and toxicological profile are equivalent. Pharmacokinetic studies have demonstrated relative bioavailability between Omeprazole capsules and OME-Mg tablet formulations"

The publicly available briefing document from Procter & Gamble for the June 21, 2002 Advisory Committee meeting on the switch stated:

As shown in table 3.1 OME-Mg has a similar bioavailability profile to the commercially available OME capsules. When OME 20 was compared to OME-Mg 20, relative areas under the curve were comparable within a fairly tight range.

At no point did Procter & Gamble assert bioequivalence. Further, demonstration of bioequivalence was not requested by FDA for approval of Prilosec OTC, nor was bioequivalence discussed during the June 21, 2002 Advisory Committee meeting where

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approval of Prilosec OTC was recommended. Mylan's correspondence adds nothing to the regulatory record, nor does the Mattingly petition.

Mylan's interest in bioequivalence is also misplaced given that the efficacy of Prilosec OTC has been clinically demonstrated, and does not rest on bioequivalence.

Mylan seems to advocate the proposition that bioequivalence is a prerequisite for products' sharing a trade name. The obvious falsity of this position is demonstrated by its necessary conclusion: Different doses of a drug could never share a trade name, since they couldn't by definition be bioequivalent.

In sum, the Mattingly petition that Mylan's letter seeks to support should be summarily denied. It does nothing more than ask, with no basis, for the Agency to rehash conclusions painstakingly reached by it and its advisory committees over years of careful consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Paul Franz', is written over the typed name. The signature is fluid and cursive.

Paul Franz

cc: Dr. Charles Ganley
Daniel Troy, Esq.
Dr. Robert Justice