



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 25, 2013

Matthew M. Malloy
Associate General Counsel
The Proctor & Gamble Company
299 East 6th St.
Cincinnati, OH 45202

Dear Mr. Malloy:

Your petition to the Food and Drug Administration requesting the Agency to continue to require similar labeling applicable to all over-the-counter ("OTC") proton pump inhibitors ("PPIs"), substantially equivalent to that approved for Prilosec OTC for subsequent OTC PPIs approved for marketing, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1286/CP1, and it was filed on 10/25/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Karen Kennard".

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)