



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 29, 2013

FILE COPY

Theodore M. Sullivan
Buchanan Ingersoll & Rooney PC
1700 K Street, N.W., Suite 300
Washington, DC 20006-3807

Dear Mr. Sullivan:

Your petition to the Food and Drug Administration on behalf of Ferring Pharmaceuticals, Inc. requesting an amended exclusivity period granted for Ferring's Prepopik™ (citric acid; magnesium oxide; sodium picosulfate) oral solution drug product (new drug application ("NDA") 202535), was received by this office on 1/29/2013. It was assigned docket number FDA-2013-P-0119/CP1, and it was filed on 1/29/2013. 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 black ink, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)