



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 31, 2013

FILE COPY

Robert Dettery
Vice President, Regulatory Affairs
Mutual Pharmaceutical Company, Inc.
1100 Orthodox Street
Philadelphia, PA 19124

Dear Mr. Dettery:

Your petition to the Food and Drug Administration requesting that FDA make a determination that the drug product, Piroxicam Capsules, 5mg is suitable for evaluation under an Abbreviated New Drug Application (ANDA), was received by this office on 05/31/2013. It was assigned docket number FDA-2013-P-0666/CP1, and it was filed on 05/31/2013. 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, 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)