



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

February 2, 2005

Michael J. Walters
President
PRG Consulting
312 Broad Armstrong Drive
Brownsboro, AL 35741

Dear Mr. Walters :

Your petition to the Food and Drug Administration requesting permission to submit an Abbreviated New Drug Application (ANDA) for a proposed new drug product Colistimethate Sodium 150 mg/2 mL Solution, was received by this office on 02/02/2005. It was assigned docket number 2005P-0050/CP 1 and it was filed on 02/02/2005. 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 "Gloria Ortega".

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0050

ACK 1