



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

March 18, 2013

**FILE COPY**

Pankaj Dave PhD.  
Vice President – Regulatory Affairs  
Emcure Pharmaceuticals USA, Inc.  
21 B Cotters Lane  
East Brunswick, NJ 08816

Dear Dr. Dave :

Your petition to the Food and Drug Administration requesting FDA to accept Abbreviated New Drug Applications (ANDAs) for Diphenhydramine Hydrochloride Injection USP, 50 mg/ml (SDV and MDV), was received by this office on 03/18/2013. It was assigned docket number FDA-2013-P-0336/CP1, and it was filed on 03/18/2013. 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)