



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

August 2, 2006

Pradeep Sanghvi, Ph.D  
MonoSol Rx, LLC.  
6560 Melton Road  
Portage, Indiana 46368

Dear Dr. Sanghvi:

Your petition requesting the Food and Drug Administration to declare that Loperamide Hydrochloride Orally Dissolving Strips 2 mg is suitable for submission as an Abbreviated New Drug Application (ANDA), was received by this office on 08/02/2006. It was assigned docket number 2006P-0305/CP1 and it was filed on 08/02/2006. 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

2006P-0305

ACK1