



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,

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

2006P-0305

ACK/