



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 2, 2006

FILE COPY


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 seek a determination that loperamide hydrochloride 2 mg orally dissolving film strip is suitable for an Abbreviated New Drug Application (ANDA), was received by this office on 03/02/2006. It was assigned docket number 2006P-0098/CP1 and it was filed on 03/02/2006. 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-0098

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