DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 28, 2013

G. Srinivas
Head of Regulatory Affairs
Zydus Pharmaceuticals (USA) Inc
73, Route 31 North
Pennington, NJ 08534

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the Agency to make a determination that Imatinib Mesylate Tablets, 300 mg is suitable for submission in an Abbreviated New Drug Application ("ANDA"), was received by this office on 8/16/2013. It was assigned docket number FDA-2013-P-1002/CP1, and it was filed on 8/16/2013. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)