DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 11, 2013

Dr. Mahendra Patel
Chief Executive Officer
Navinta LLC
1499 Lower Ferry Road
Ewing, NJ 08618

Dear Dr. Patel:

Your petition to the Food and Drug Administration requesting that FDA find the Ganciclovir Injection, 500 mg/10 ml (50mg/mL) Solution, is suitable for submission as an Abbreviated New Drug Application (ANDA), was received by this office on 08/29/2013. It was assigned docket number FDA-2013-P-1061/CP1, and it was filed on 08/29/2013. 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)