DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 25, 2013

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Dear Mr. Karst:

Your petition to the Food and Drug Administration requesting a determination that the 12 mg strength of Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s ("Janssen's") INVEGA (paliperidone) Extended-release Tablets, approved under New Drug Application ("NDA") No. 021999, was not discontinued for safety or effectiveness reasons, was received by this office on 06/25/2013. It was assigned docket number FDA-2013-P-0775/CP1, and it was filed on 06/25/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)