DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 9, 2013

Joy J. Liu, Esq.
Ropes & Gray, LLP
One Metro Center, Suite 900
700 12th Street, N.W.
Washington, D.C. 20005

Dear Ms. Liu:

Your petition to the Food and Drug Administration on behalf of Janssen Research and Development, L.L.C. requesting FDA to adopt specific bioequivalence requirements in its review of proposed generic and follow-on versions of INVEGA ® SUSTENNA ®, was received by this office on 05/09/2013. It was assigned docket number FDA-2007-D-0369/CP, and it was filed on 05/09/2013. 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)