DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 5 2013

Joy J. Liu
Ropes & Gray, LLP
One Metro Center, Suite 900
700 12th Street, N.W.
Washington, D.C. 20005-3948

Re: Docket No. FDA-2013-P-0608[1]

Dear Ms. Liu:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on May 9, 2013. Your petition requests that FDA adopt and apply certain bioequivalence requirements in its review of applications for generic versions of Invega Sustenna (paliperidone palmitate).

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

[1] In your letter, you reference docket number FDA-2007-D-0369, which was the docket number erroneously assigned to your petition. Please note that the correct docket number is FDA-2013-P-0608