DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 12 2013

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

Re: Docket No. FDA-2013-P-0775

Dear Mr. Karst:

This letter responds to your citizen petition received on June 25, 2013, requesting that the Food and Drug Administration (FDA) determine whether INVEGA (paliperidone) extended-release tablet, 12 milligrams (mg) (new drug application 21-999), was discontinued for safety or effectiveness reasons.

The FDA has reviewed its records and determined that INVEGA (paliperidone) extended-release tablet, 12 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain INVEGA (paliperidone) extended-release tablets, 12 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-3977.

Sincerely,

Linda Jong

Linda Jong
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure