



Blessy Johns
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Rd.
East Windsor, NJ 08520

June 24, 2024

Re: Docket No. FDA-2024-P-2272

Dear Ms. Johns:

This letter responds to your citizen petition received on May 7, 2024, requesting that the Food and Drug Administration (FDA) determine whether Invega (paliperidone) extended-release tablet, 1.5 milligrams (mg); new drug application 021999 of Janssen Pharmaceuticals Inc., has been voluntarily withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that Invega (paliperidone) extended-release tablet, 1.5 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Invega (paliperidone) extended-release tablet, 1.5 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) 796-8363.

Sincerely,

Stacy Kane
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure