



## URGENT DRUG RECALL

October 20, 2009

Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., Titusville, NJ, is notifying all US Direct Purchasers and Retail / Institutional Pharmacies of a voluntary recall of the product listed below. No other product marketed by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. is impacted. This voluntary recall is being conducted in coordination with the U.S. Food and Drug Administration.

Product	NDC Number	Lot Number
INVEGA® (Paliperidone) 6 mg Extended-Release Tablets (30 count bottle)	50458-551-01	9KG024
Manufactured By: Janssen Cilag Manufacturing, LLC Gurabo PR, 00778-9629		

### REASON FOR MARKET ACTION

The lot of INVEGA® (Paliperidone) 6 mg Extended-Release Tablets listed above was coated with an incorrect pink color but is correctly imprinted with "PALI 6". The correct color for INVEGA® (Paliperidone) 6 mg Extended-Release Tablets is beige.

### HEALTH ASSESSMENT

The recalled lot identified above is the correct strength (6 mg), has correct labeling and correct packaging, with the strength correctly imprinted on the tablets as "PALI 6". The pink coloring used is an approved color for a different dosage of the same product line. Therefore, patients who take an incorrectly colored pink 6 mg tablet instead of a beige 6 mg tablet are not considered to be at increased risk for adverse reactions.

There could be a risk if patients stopped taking INVEGA® (Paliperidone) 6 mg Extended-Release Tablets due to concerns over the color of the tablets and therefore, the lot listed above should not be further dispensed. There could also be a risk if the strength of the tablet is misinterpreted such that an incorrect dose were dispensed or taken due to the incorrect color.

### ACTION TO BE TAKEN:

1. Stop dispensing or distributing and quarantine the INVEGA® (Paliperidone) 6 mg Extended-Release lot listed above.
2. Please carry out a physical count of your affected inventory of the indicated INVEGA® lot and record this data on the Business Reply Card that is included with this letter. Return the reply to Stericycle, Inc. The Business Reply Card is postage paid.
3. **If you DO NOT have the recalled lot**, you must still complete the enclosed Business Reply Card and return it to Stericycle, Inc.
4. **If you DO have product to return**, complete the enclosed Packing Slip and return along with your product. Please attach the prepaid UPS Return Service shipping label to the outside of the return carton and return to:

**Stericycle, Inc.**  
**ATTN: 2048**  
**2670 Executive Drive, Suite A**  
**Indianapolis, IN 46241**

### ADDITIONAL INFORMATION

- Credit for returned product will be issued to the direct wholesale and retail chain pharmacy accounts at the current list price. For assistance with product return, contact Stericycle at 1-877-546-0444 (Monday – Friday, 8 am – 5 pm EST).
- If you have product related questions please contact The Customer Communications Center at 1-800-526-7736 (1-800-JANSSEN) (Monday – Friday, 9 am – 5 pm EST) or visit [www.invega.com](http://www.invega.com).