

Dr E Abadie
CHMP Chairman
EMA
7 Westferry Circus
Canary Wharf
London E14 4HB

15th December 2008

Dear Dr Abadie:

INVEGA (paliperidone) prolonged-release tablet

Submission /0022 - EMA/H/C/746/II/0019: Type II Variation to add a new indication for the treatment of acute manic episodes associated with bipolar I disorder.

Procedure No. EMA/CHMP/746; Licence No. EU/1/07/395/001-076

I would like to inform you that Janssen-Cilag International N.V. has taken the decision to withdraw the above application with immediate effect.

This withdrawal is based on the Rapporteur's and Co-Rapporteur's Assessment Reports indicating that the data provided to date were not sufficient to support approval for this indication and the company's assessment that it is not in a position to adequately address the questions at this time.

We reserve the right to make further submissions for this indication at a future date.

I agree for this letter to be published on the EMA website.

Yours sincerely,

European Regulatory Affairs
Johnson & Johnson Pharmaceutical R&D
For and on behalf of JANSSEN CILAG INTERNATIONAL N.V.