DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-304

CORRECTION TO
NDA APPROVAL LETTER

Ortho-McNeil-Janssen Pharmaceuticals, Inc.
c/o Johnson & Johnson Pharmaceutical Research
& Development, L.L.C.
1125 Trenton-Harbourton Road, P.O. Box 200
Titusville, NJ 08560-0200

Attention: Kathleen F. Dusek, R.Ph., RAC
Associate Director, Regulatory Affairs

Dear Ms. Dusek:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for tapentadol.

We also refer to your labeling submission dated December 15, 2008.

As discussed in your December 2, 2008, telephone conversation with Matthew Sullivan of FDA, tapentadol, which is not currently scheduled under the Controlled Substances Act, was approved on November 20, 2008, with labeling that refers to CSA scheduling. Your December 15 submission includes the package insert and medication guide revised to make a few minor editorial changes, and to exclude the references to CSA scheduling. The carton and immediate container labels have not been revised, because they do not include references to CSA scheduling.

We have completed our review of your December 15 labeling submission and consider this labeling the approved package insert and Medication Guide for this product.

If you have any questions, call Matt Sullivan, Regulatory Project Manager, at (301) 796-1245.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures
Package Insert dated December 15, 2008
Medication Guide dated December 15, 2008

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport
12/24/2008 01:56:44 PM
Signed for Curtis Rosebraugh, M.D.