DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-106/S-002
NDA 22-106/S-005

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Catherine Ellis
Director, North American Regulatory Liaison
920 U.S. Highway 202
P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Ellis:

Please refer to your supplemental new drug applications (sNDA) dated and received April 10, 2008 (S-002), and dated and received October 30, 2008 (S-005), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DORIBAX™ (doripenem for injection).

NDA 22-106/S-002: This "Changes Being Effected" supplemental new drug application added the terms neutropenia and leucopenia to the postmarketing experience subsection of ADVERSE REACTIONS section. For this supplement, your submission dated December 24, 2008, constituted a complete response to our November 3, 2008 action letter.

NDA 22-106/S-005: This "Changes Being Effected" supplemental new drug application revised the label to describe interaction of doripenem with valproic acid. For this supplement, we acknowledge receipt of your amendment dated April 8, 2009.

We completed our review of both these applications as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert submitted on April 8, 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-106/S-002 and NDA 22-106/S-005."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05

5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susmita Samanta, MD, Regulatory Project Manager, at 301-796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Sumathi Nambiar

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