



NDA 021337/S-045

SUPPLEMENT APPROVAL

Merck, Sharp & Dohme Corp.
A subsidiary of Merck & Co, Inc.
Attention: Donna Zacholski
Director, Worldwide Regulatory Affairs
351 N. Sumneytown Pike
P.O. Box 1000, UG2D-68
North Wales, PA 19454-2505

Dear Ms. Zacholski:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 31, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INVANZ (ertapenem) Injection, 1 gram.

This Prior Approval supplemental new drug application revises the container labels and carton (tray) labeling.

APPROVAL & LABELING

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on August 31, 2017, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 021337/S-045.**” Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

Carton, Container Labeling

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

/s/

JOSEPH G TOERNER
09/08/2017