DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205435/S-006

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp
A Subsidiary of Merck & Co., Inc.
Attention: Neetesh Bhandari, BVSC, PhD, DABT
Director, Global Regulatory Affairs
351 N. Sumneytown Pike, PO Box 1000
UG2CD-48
North Wales, PA 19454-2505

Dear Dr. Bhandari:

Please refer to your Supplemental New Drug Application (sNDA) dated May 24 2016, received May 24, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sivextro (tedizolid phosphate) Tablets, 200 mg.

This Prior Approval supplemental new drug application provides for a physician sample packet containing one tablet.

APPROVAL & LABELING

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

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Sumati Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Carton Labeling & Blister Card

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
09/16/2016