NDA 204384/S-012

**SUPPLEMENT APPROVAL**

Janssen Research & Development, LLC
Attention: Michele Dias, MSc
Associate Director, Global Regulatory Affairs
920 Route 202, South
PO Box 300
Raritan, NJ 08869

Dear Ms. Dias:

Please refer to your supplemental new drug application (sNDA) dated and received August 14, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sirturo (bedaquiline) Tablets, 100 mg.

This "Changes Being Effected" supplemental new drug application provides for updating the equivalency statement on the bottle label to align with the USP Salt Policy.

## APPROVAL & LABELING

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

## CARTON AND CONTAINER LABELING

We acknowledge your August 14, 2019, submission containing final printed container labeling.

## 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 Fariba Izadi, PharmD, Acting Safety Regulatory Project Manager, at (301) 796-0563.

Sincerely,

*{See appended electronic signature page}*

Joseph G. 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:

- Container Labeling

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/s/

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JOSEPH G TOERNER
08/15/2019 01:26:40 PM