NDA 210910/S-001

SUPPLEMENT APPROVAL

Cosmo Technologies, Ltd.
Attention: Steven Kradjian, RAC
President and U.S. Agent
5414 Oberlin Drive, Suite 130
San Diego, CA 92121

Dear Mr. Kradjian:

Please refer to your supplemental new drug application (sNDA) dated January 14, 2019, received January 15, 2019 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aemcolo (rifamycin) Delayed-Release Tablets, 194 mg.

This Changes Being Effected supplemental new drug application provides for revisions to the expiration date formatting on the carton and container labels, and removal of the barcode from only the sample blister pack.

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 January 18, 2019, submission containing final printed carton and 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 Naseya Minor, Regulatory Project Manager, at 301-796-0756.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
07/12/2019 01:54:47 PM