DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-703/S-016

SUPPLEMENT APPROVAL

SmithKline Beecham (Cork) Ltd.
Attention: Dawn Adsit, RAC
Senior Associate, Global Regulatory Affairs
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Adsit:

Please refer to your Supplemental New Drug Application (sNDA) dated November 14, 2014, received November 14, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BACTROBAN (mupirocin calcium) nasal ointment.

We acknowledge receipt of your amendment dated May 8, 2015.

This "Prior Approval" supplemental new drug application provides for conversion of the labeling to the Physicians Labeling Rule (PLR) format.

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 text and with the following revision indicated in the enclosed labeling.

Specifically, we recommend omitting the drug product strength 2% from the Product Title (*Drug names, dosage form, route of administration, and controlled substance symbol)* because the regulations under 21 CFR 201.57(a)(2) do not include the drug product strength as a component of this heading in highlights (HL). We note that the drug product strength appears under the Dosage Forms and Strengths heading in HLs per the regulations under 21 CFR 201.57(a)(8). Omitting strengths from the product title avoids redundancy within Highlights.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the

addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Maureen Dillon-Parker, Regulatory Project Manager, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling

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
05/14/2015