DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205223/S-002

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
REQUIREMENT**

Chemo Research SL
Attention: Babu Lad
VP Regulatory Affairs
180 Park Avenue, Suite 101
Florham Park, NJ 07932

Dear Mr. Lad:

Please refer to your Supplemental New Drug Application (sNDA) dated February 5, 2018, received February 5, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nuvessa (metronidazole vaginal gel 1.3%).

This Prior Approval supplemental new drug application provides for labeling changes regarding the use of Nuvessa in adolescent females 12 to less than 18 years of age with bacterial vaginosis. This trial was conducted to fulfill the following Postmarketing Requirement listed in our March 24, 2014, letter:

2123-001: A study to evaluate the safety of metronidazole gel 1.3% single dose in the treatment of bacterial vaginosis in females 12-<18 years of age.

Specifically, the **HIGHLIGHTS, DOSAGE AND ADMINISTRATION (1), ADVERSE REACTIONS (6), Clinical Trials Experience (6.1)** subsection, **USE IN SPECIFIC POPULATIONS (8),** and the **PATIENT PACKAGE INSERT (PPI)** sections of the labeling have been updated to reflect use in the pediatric population 12 to less than 18 years of age.

## 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.

We also note that you have fulfilled the pediatric study requirements for all relevant pediatric age groups for this application. This completes your postmarketing requirement acknowledged in our March 24, 2014, letter.

## 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 prescribing information), 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 include 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 Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 796-1202.

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(S):
Content of Labeling

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**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.**

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/s/

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SUMATHI NAMBIAR
08/03/2018