DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22268/S-003

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Bijal Pandhi, Pharm.D.
Manager, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Pandhi:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 16, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Coartem (artemether 20 mg/lumefantrine 120 mg) Tablets.

We acknowledge receipt of your amendment dated June 18, 2012.

This supplemental new drug application provides for the following revisions to the product labeling based on our review of the study reports dated March 14 and June 29, 2011, for Postmarketing Requirements #6, #11, #12, and #13, listed in our April 7, 2009, approval letter:

HIGHLIGHTS OF PRESCRIBING INFORMATION: RECENT MAJOR CHANGES, CONTRAINDICATIONS, and DRUG INTERACTIONS

CONTRAINDICATIONS
- 4.2 Strong CYP3A4 Inducers

WARNINGS AND PRECAUTIONS
- 5.3 Drug Interactions with CYP3A4

DRUG INTERACTIONS
- 7.1 Rifampin
- 7.3 Anti-Retroviral Drugs
- 7.5 Hormonal Contraceptives

CLINICAL PHARMACOLOGY/12.3 Pharmacokinetics
1. Biotransformation
2. Drug Interactions
    - Rifampin (strong CYP3A4 inducer)
    - Anti-Retroviral Drugs
    - Hormonal Contraceptives

PATIENT COUNSELING INFORMATION

This supplemental new drug application also provides for several editorial revisions to product labeling that are not captured in the sections noted above.

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, submitted June 18, 2012.

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 and text for the patient 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 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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, 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:
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
08/06/2012