DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 08316/S-023

SUPPLEMENT APPROVAL

Sanofi-Aventis U.S. LLC, a Sanofi Company
Attention: John Cook
Senior Director, Global Regulatory Affairs Marketed Product
55 Corporate Drive, Mail Stop 55C-205A
Bridgewater, NJ 08807

Dear Mr. Cook:

Please refer to your Supplemental New Drug Application (sNDA) dated October 12, 2016, received October 16, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PRIMAQUINE (primaquine phosphate) Tablets 26.3 mg.

This Prior Approval supplemental new drug application provides for the revisions to the **WARNINGS, PRECAUTIONS and REFERENCES** sections of the package insert as follows:

WARNINGS
The **Usage in Pregnancy** subsection was revised to include information on the potential for adverse genetic and reproductive effects associated with Primaquine treatment.

The **Use in Females and Males of Reproductive Potential** subsection was added to include information on the potential reproductive effects associated with Primaquine treatment.

PRECAUTIONS
The **Carcinogenesis, Mutagenesis, Impairment of Fertility** subsection, and the **Animal Pharmacology and/or Animal Toxicology** subsection were added and revised to include information on potential genotoxicity and reproductive toxicity.

REFERENCES
This section was added and updated.

Additionally, minor editorial revisions have been made throughout the package insert.

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 with minor editorial revisions.

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

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:
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/

JOSEPH G TOERNER
06/22/2017