DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21799/S-024

SUPPLEMENT APPROVAL

Mutual Pharmaceutical Company, Inc.
Attention: Linda Plocher
Manager, Electronic Submissions
1100 Orthodox Street
Philadelphia, PA 19124

Dear Ms. Plocher:

Please refer to your Supplemental New Drug Application (sNDA) dated January 2, 2014, received January 2, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Qualaquin (quinine sulfate) Capsules, 324 mg.

We acknowledge receipt of your amendment dated March 28, 2014.

This "Changes Being Effected" supplemental new drug application provides for the following:

> Changing the container label to market the product by Caraco Pharmaceutical Laboratories Ltd. ("Caraco") instead of AR Scientific Inc.
>
> Replacing the NDC number and the AR Scientific logo with the SunPharma logo, revising the design, the distribution by information, and the package insert to update information pertinent to Caraco.

The **HIGHLIGHTS OF PRESCRIBING INFORMATION, RECENT MAJOR CHANGES** Section has been removed because all Recent Major Changes previously listed were more than one year old.

In addition, the product labeling for format has been updated to be consistent with the current guideline for Physician Labeling Rule (PLR), specifically the Selected Requirements of Prescribing Information (SRPI).

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21799/S-024**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container 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
07/02/2014