DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-799/S-015 **SUPPLEMENT APPROVAL**

AR Holding Company, Inc.
Attention: Mr. Robert Dettery
Vice-President, Regulatory Affairs
1100 Orthodox Street
Philadelphia, PA 19124

Dear Mr. Dettery:

Please refer to your supplemental new drug application dated and received December 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for QUALAQUIN® (quinine sulfate USP) Capsules, 324 mg.

This Prior Approval Supplemental new drug application provides for:

> Revisions to the immediate container labels (30 capsules, 100 capsules, 500 capsules, and 1000 capsules) to include the addition of the following statement:
>
> DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon immediate container labels.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed immediate container labels in **full color** that are identical to the enclosed 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* 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 21-799/S-015."** Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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) 796-1600.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Deputy Director for Safety
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:
Immediate Container Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21799	SUPPL-15	AR HOLDING CO INC	QUALAQUIN SULFATE CAPSULES 324MG

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

OZLEM A BELEN
01/22/2010