DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020485/S-009

SUPPLEMENT APPROVAL

Johnson & Johnson Healthcare Products
Division of McNeil-PPC, Inc.
Attention: Dawn M. Jackman
Associate Director, Global Regulatory Affairs
185 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Jackman:

Please refer to your Supplemental New Drug Application (sNDA) dated October 19, 2011, received October 20, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Visine®-A® (pheniramine maleate, 0.3%, and naphazoline hydrochloride, 0.025%) ophthalmic solution.

We acknowledge receipt of your amendments dated June 20 and September 7, 2012.

The June 20, 2012, submission constituted a complete response to our April 17, 2012, action letter.

This "Prior Approval" supplemental new drug application proposes the following changes: the addition of "Multi-Action" before the existing "Eye Allergy Relief" statement to read "Multi-Action Eye Allergy Relief" on the package insert and the Principal Display Panel (PDP) of the immediate container (bottle) and carton.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to: ½ fl. oz. (15 mL) carton and bottle label and package insert submitted on June 20, 2012, and the twin pack carton label submitted on September 7, 2012, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted 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 (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 Labeling for approved NDA 020485/S-009**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 questions, contact Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling, Package Insert

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

/s/

JOEL SCHIFFENBAUER
12/18/2012