DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020485/S-013

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.,
McNeil Consumer Healthcare Division
Attention: Jennifer Norman, RPh
Director, Regulatory Affairs
7050 Camp Hill Road
Mail Stop 111
Fort Washington, PA 19034-2299

Dear Ms. Norman:

Please refer to your supplemental New Drug Application (sNDA) dated and received December 20, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Visine (naphazoline hydrochloride 0.025% and pheniramine maleate 0.3%) ophthalmic solution.

This "Prior Approval" supplemental new drug application provides for the following changes to the Principal Display Panel:

- Changes the proprietary name from Visine®-A to Visine®
- Revises the established name within the Statement of Identity consistent with current USP drug product title to "naphazoline HCl and pheniramine maleate ophthalmic solution"
- Changes the statement "Multi-Action Eye Allergy Relief" to "Allergy Eye Relief Multi-Action"
- Adds the statement "Original Prescription Strength"
- Changes the claim "Clinically proven to relieve itchy, red, allergy eyes" to "Clinically proven to relieve red, itchy eyes"
- Changes the graphic/trade dress

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling submitted on October 12, 2018 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable as follows:

SKU	Date Submitted
15 mL carton	October 12, 2018
30 mL carton (two 15 mL immediate container bottles, "twin pack")	October 12, 2018
15 mL immediate container bottle (front label)	October 12, 2018
15 mL immediate container bottle (back label)	October 12, 2018

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020485/S-013**." 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 any questions, call Jung Lee, Regulatory Project Manager, at (301) 796-3599.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KAREN M MAHONEY
10/17/2018