DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020485/S-011

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
Attention: Joseph Chmielewski, RAC
Associate Director, Regulatory Affairs
199 Grandview Road
Skillman, NJ 08558

Dear Mr. Chmielewski:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 26, 2016, and your amendments, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Visine-A (pheniramine maleate 0.3%; naphazoline HCl 0.025%) Eye Drops.

This "Prior Approval" supplemental new drug application provides for the changes to the labeling, including:

- Changes to the Drug Facts Label (DFL):
  - Under "Ask a doctor before use if you have", the statement "trouble urinating due to an enlarged prostate gland" has been revised to "trouble urinating"
  - Under "When using this product", the statement "pupils may become enlarged temporarily" has been revised to "pupils may become enlarged temporarily causing light sensitivity"
  - "Some users may experience a brief tingling sensation" was relocated to the "When using this product" section of the DFL.

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 the enclosed labeling: the 1/2 fl. oz. (15 mL) carton and 2 x 1/2 fl. oz. twin pack carton submitted August 16, 2016; and the 1/2 fl. oz. (15 mL) bottle – front panel and 1/2 fl. oz. (15 mL) bottle – back panel submitted May 23, 2016; and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL 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-011**." 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 CAPT Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

KAREN M MAHONEY
08/26/2016
Signing for Dr. Valerie Pratt