NDA 022305/S-007

SUPPLEMENT APPROVAL

Niagara Pharmaceuticals Inc.
Attention: Thomas Padula
c/o Schiff & Company
Vice President, Regulatory Compliance
583 Mountain Avenue
North Caldwell, NJ 07006

Dear Thomas Padula:

Please refer to your supplemental new drug application (sNDA) dated February 12, 2025, received February 14, 2025, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pur-Wash (purified water) ophthalmic solution, 98.3%.

This Prior Approval supplemental new drug application provides for labeling revisions to the drug facts label (DFL) and principal display panel (PDP) as requested in FDA's January 22, 2025, prior approval supplement request.

APPROVAL & LABELING

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 enclosed agreed-upon labeling with minor editorial revisions listed below.

- For NDC #: 65785-169-01 and 65785-169-04 labels (1 fl oz and 4 fl oz immediate containers, respectively):
  - In the "***Questions?***" section, include a period after the letter "m" to read as: "a.m." and "p.m.".

- For NDC #: 65785-162-02 label (16 fl oz immediate container):
  - In the "***Directions***" section, remove the period at the end of the second bulleted statement.

- For NDC #: 65785-166-01 label (16 fl oz immediate container):
  - In the "***Other information***" section, revise the bulleted statement from: "■ do not use if the tamper-evident ring is broken" to: "■ do not use if the tamper-evident ring is missing or broken".

- For NDC #: 65785-168-02 label (32 fl oz immediate container):

- In the "***Other information***" section, remove the extra space in the word "bottl e" to read as: "bottle" at the end of the first bulleted statement.

LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling (except for the minor revisions), as described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
1 fl oz (30 mL) immediate container • NDC: 65785-160-01 • NDC: 65785-169-01	June 17, 2025
4 fl oz (118 mL) immediate container • NDC: 65785-160-02 • NDC: 65785-169-04	June 17, 2025
8 fl oz (236 mL) immediate container • NDC: 65785-162-01	June 17, 2025
16 fl oz (473 mL) immediate container • NDC: 65785-162-02 • NDC: 65785-168-01 • NDC: 65785-166-01	June 17, 2025
32 fl oz (946 mL) immediate container • NDC: 65785-168-02 • NDC: 65785-166-02	June 17, 2025

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 022305/S-007**." Approval of this submission by FDA is not required before the labeling is used.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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 Suzanne Strayhorn, Senior Regulatory Project Manager, at (240) 402-4247.

Sincerely,

{See appended electronic signature page}

Melanie Blank, M.D., M.S.
Deputy Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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/

MELANIE J BLANK
06/26/2025 08:19:20 AM