NDA 209090/S-008

SUPPLEMENT APPROVAL

Chattem, Inc., d/b/a Opella
Attention: Michael Kenny
Regulatory Affairs Lead
21 South Street
Morristown, NJ 07960

Dear Michael Kenny:[1]

Please refer to your supplemental new drug application (sNDA) dated and received March 4, 2026, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xyzal Allergy 24HR (levocetirizine dihydrochloride) oral solution, 2.5 mg per 5 mL.

This "Prior Approval" supplemental new drug application provides for the adult variants to be marketed in addition to the children's products.

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.

Submitted Draft Labeling	Date submitted
bubble gum flavor 5 fl. oz outer container	7/7/2026
bubble gum flavor 5 fl. oz bottle label (immediate container)	8/26/2026
berry flavor 5 fl. oz outer container	7/7/2026
berry flavor 5 fl. oz bottle label (immediate container)	8/26/2026
bubble gum flavor 10 fl. oz outer container	7/7/2026
bubble gum flavor 10 fl. oz bottle label (immediate container)	8/26/2026
berry flavor 10 fl. oz outer container	7/7/2026
berry flavor 10 fl. oz bottle label (immediate container)	8/26/2026

[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.

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 enclosed labeling described in the table below.

The FPL should be submitted electronically according to guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[2] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 209090/S-008**." 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 FDA.gov.[3] Information on submitting SPL files using eLIST may be found in 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).

[2] 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.

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

If you have any questions, contact Tam Dinh, PharmD, Regulatory Project Manager, at 240-402-6284 or Tam.Dinh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ovidiu Galescu, MD
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
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/

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