NDA 209089/S-010

SUPPLEMENT APPROVAL

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

Dear Wendy McManus:

Please refer to your supplemental new drug application (sNDA) dated and received December 2, 2025, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xyzal Allergy 24HR (levocetirizine) tablet, 5 mg.

This "Changes Being Effected" supplemental new drug application provides for a revision to the Drug Facts label to include a warning about new onset pruritus that occurs after discontinuation of levocetirizine, in response to the Agency's CBE Supplement Request letter dated July 11, 2025. It also provides for various graphic and text revisions to the labeling.

APPROVAL & LABELING

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

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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the labeling listed in the table below:

Submitted Draft Labeling	Date submitted
5-count carton (India country of origin)	12/2/2025
10-count carton (India country of origin)	12/2/2025
20-count carton (India country of origin)	12/2/2025
35-count carton (India country of origin)	12/2/2025
55-count carton (India country of origin)	12/2/2025
80-count carton (India country of origin)	12/2/2025
110-count stretchcard back (India country of origin)	12/2/2025

35-count bottle (India country of origin)	12/2/2025
55-count bottle (India country of origin)	12/2/2025
80-count bottle (India country of origin)	12/2/2025

We remind you to submit identical labeling with Switzerland as the country of origin with the FPL. 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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 209089/S-010**." 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.[2] 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).

[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.

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

If you have any questions, contact Helen Lee, Safety Regulatory Project Manager, at 301-796-6848 or Helen.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Dorothy Chang, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- 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/

DOROTHY N CHANG
05/20/2026 09:41:31 AM