NDA 209090/S-007

SUPPLEMENT APPROVAL

Chattem, Inc., d/b/a Sanofi Consumer Healthcare
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 September 11, 2025, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Xyzal Allergy 24 HR (levocetirizine dihydrochloride) oral solution, 2.5 mg per 5 mL (0.5 mg/mL).

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, as amended. 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
bubble gum flavor 5 fl. oz outer container	12/9/2025
bubble gum flavor 5 fl. oz bottle label (immediate container)	12/9/2025
grape flavor 5 fl. oz outer container	12/9/2025
grape flavor 5 fl. oz bottle label (immediate container)	12/9/2025
bubble gum flavor 10 fl. oz outer container	12/9/2025

bubble gum flavor 10 fl. oz bottle label (immediate container)	12/9/2025
grape flavor 10 fl. oz outer container	12/9/2025
grape flavor 10 fl. oz bottle label (immediate container)	12/9/2025

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 209090/S-007**." 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 are 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).

[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, please 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
03/05/2026 03:03:01 PM