NDA 209090/S-003

SUPPLEMENT APPROVAL

Chattem Inc. d/b/a Sanofi Consumer Healthcare
Attention: Monika A. Socha
Regulatory Lead – Allergy
CHC US Scientific Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Socha:

Please refer to your supplemental new drug application (sNDA) dated and received October 25, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Xyzal Allergy 24HR (levocetirizine dihydrochloride) oral solution, 2.5 mg per 5 mL (0.5 mg per mL).

We acknowledge receipt of your amendment dated March 15, 2022, which constituted a resubmission after withdrawal of the sNDA.

This "Prior Approval" supplemental new drug application provides for the addition of a new grape flavor variant of Children's Xyzal Allergy 24HR, to be marketed in addition to the currently approved tutti frutti flavor.

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 identical to the enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. We remind you to remove the "NEW FLAVOR!" flag from the labeling six months after the marketing start date.

Submitted Draft Labeling	Date submitted
grape flavor 5 fl. oz outer container	6/21/22
grape flavor 5 fl. oz bottle label (immediate container)	6/21/22

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-003.** 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 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, call Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
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/

SHERRY A STEWART
07/13/2022 09:22:56 AM

NUSHIN F TODD
07/13/2022 09:32:05 AM