NDA 201373/S-012

SUPPLEMENT APPROVAL

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

Dear Ms. Socha-Behot:

Please refer to your supplemental new drug application (sNDA) dated and received on August 16, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Allegra Allergy and Children's Allegra Hives (fexofenadine hydrochloride) oral suspension, 30 mg per 5 mL.

This "Prior Approval" supplemental new drug application provides for addition of a berry flavored fexofenadine hydrochloride oral suspension, 30 mg per 5 mL, in 4 ounce and 8 ounce sizes.

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. The "New!" flag on the Children's Allegra® Hives (fexofenadine hydrochloride) oral suspension labeling should be removed six months after marketing.

Submitted Draft Labeling	Dates Submitted
Allergy berry flavor 4 fl. oz outer container	12/6/22
Allergy berry flavor 4 fl. oz bottle label (immediate container)	8/16/22
Allergy berry flavor 8 fl. oz outer container	12/6/22
Allergy berry flavor 8 fl. oz bottle label (immediate container)	8/16/22
Hives berry flavor 4 fl. oz outer container	12/6/22

Hives berry flavor 4 fl. oz bottle label (immediate container)	8/16/22
Hives berry flavor 8 fl. oz outer container	12/6/22
Hives berry flavor 8 fl. oz bottle label (immediate container)	8/16/22

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 201373/S-012**." 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.

[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

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656 or email at Phong.Pham@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
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/

NUSHIN F TODD
12/16/2022 05:01:26 PM