



NDA 021909/S-019

## SUPPLEMENT APPROVAL

Chattem, Inc., d/b/a Opella  
Attention: Carolyn Zlogar  
Regulatory Lead, Global Brands  
21 South Street  
Morristown, NJ 07960

Dear Carolyn Zlogar:

Please refer to your supplemental new drug application (sNDA) dated and received January 6, 2026, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Allegra Allergy (fexofenadine hydrochloride) orally disintegrating tablet, 30 mg.

This "Prior Approval" supplemental new drug application provides for updates to the principal display panel on carton 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 following:

<b>Submitted Labeling</b>	<b>Date Submitted</b>
24-ct outer container label (carton)	March 25, 2026
6-ct immediate container label (blister)	May 15, 2026

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 021909/S-019.**” Approval of this submission by FDA is not required before the labeling is used.

In your January 6, 2026, cover letter, you formally requested the Agency remove the following stock keeping unit from NDA 021909:

- 12-ct outer container label (carton)

If you wish to reintroduce the discontinued stock keeping unit to the U.S. market, a new submission to the FDA is required.

## **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.<sup>2</sup> 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).

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<sup>1</sup> 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>.

<sup>2</sup> <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](mailto:Tam.Dinh@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

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**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.**  
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/s/  
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