NDA 020872/S-047

SUPPLEMENT APPROVAL

Chattem, Inc. d/b/a Sanofi Consumer Healthcare
Attention: Monika Socha-Behot
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 October 14, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Allegra Allergy 24HR and Allegra Hives 24HR (fexofenadine hydrochloride) tablet, 180 mg.

We acknowledge receipt of your amendment dated February 24, 2023, which constituted a complete response to our February 13, 2023, action letter.

This "Prior Approval" supplemental new drug application provides for addition of (b) (4) as an alternate manufacturing site for drug substance, fexofenadine hydrochloride.

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 with minor editorial revisions listed below.

On the 110-count outer carton principal display panel, include an actual size image of the tablet along with the statement "actual size" adjacent to the tablet image in the final printed labeling.

LABELING

Submit final printed labeling (FPL), with the revisions listed above, 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.

Submitted Draft Labeling	Date submitted
Allegra Allergy 24HR - 180mg 1ct carton sample	10/14/22
Allegra Allergy 24HR - 180mg 2ct carton sample	10/14/22
Allegra Allergy 24HR - 180mg 5ct carton	10/14/22
Allegra Allergy 24HR - 180mg 5ct carton sample	10/14/22
Allegra Allergy 24HR - 180mg 15ct carton	10/14/22
Allegra Allergy 24HR - 180mg 30ct carton	10/14/22
Allegra Allergy 24HR - 180mg 30ct container	10/14/22
Allegra Allergy 24HR - 180mg 40ct carton bonus pack	10/14/22
Allegra Allergy 24HR - 180mg 40ct container bonus pack	10/14/22
Allegra Allergy 24HR - 180mg 45ct carton	10/14/22
Allegra Allergy 24HR - 180mg 45ct container	10/14/22
Allegra Allergy 24HR - 180mg 55ct container club pack	10/14/22
Allegra Allergy 24HR - 180mg 60ct carton	10/14/22
Allegra Allergy 24HR - 180mg 60ct container	10/14/22
Allegra Allergy 24HR - 180mg 70ct carton	10/14/22
Allegra Allergy 24HR - 180mg 70ct container	10/14/22
Allegra Allergy 24HR - 180mg 90ct carton value pack	10/14/22
Allegra Allergy 24HR - 180mg 90ct container value pack	10/14/22
Allegra Allergy 24HR - 180mg 100ct carton value pack	10/14/22
Allegra Allergy 24HR - 180mg 100ct container value pack	10/14/22
Allegra Allergy 24HR - 180mg 110ct stretch card club pack	10/14/22
Allegra Hives 24HR - 180mg 5ct carton sample	10/14/22
Allegra Hives 24HR - 180mg 5ct carton	10/14/22
Allegra Hives 24HR - 180mg 10ct carton	10/14/22
Allegra Hives 24HR - 180mg 15ct carton	10/14/22
Allegra Hives 24HR - 180mg 30ct carton	10/14/22
Allegra Hives 24HR - 180mg 30ct container	10/14/22
Allegra Hives 24HR - 180mg 60ct carton	10/14/22
Allegra Hives 24HR - 180mg 60ct container	10/14/22

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 020872/S-047**." 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.

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).

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[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 or email 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
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling