



NDA 020872/S-046

SUPPLEMENT APPROVAL

Sanofi-Aventis U.S. LLC
Attention: Michelle (Shelly) Turula, MS
Regulatory Lead, North America Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Turula:

Please refer to your supplemental new drug application (sNDA) dated and received April 15, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Allegra Hives (fexofenadine hydrochloride) tablet, 180 mg.

This "Prior Approval" supplemental new drug application provides for updated labeling for the previously approved (not-yet-marketed) Allegra Hives line extension.

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.

Submitted Draft Labeling	Date Submitted
5-count blister card	4/15/2021
30-count bottle	4/15/2021
45-count bottle	4/15/2021
60-count bottle	4/15/2021
5-count carton	6/11/2021
10-count carton	6/11/2021
15-count carton	6/11/2021
30-count carton	6/11/2021
45-count carton	6/11/2021
60-count carton	6/11/2021

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-046.**” Approval of this submission by FDA is not required before the labeling is used.

As a reminder, remove any “New!” flags on your product labeling after 6 months of marketing.

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

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>

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).

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
Acting Director
Division of Nonprescription Drugs I
Office of Nonprescription 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
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