NDA 201373/S-11

**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 November 20, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Allegra Allergy (fexofenadine hydrochloride) oral suspension, 30 mg per 5 mL.

This "Prior Approval" supplemental new drug application provides for the introduction of a new grape flavor to replace the raspberry cream flavor in the original formulation. Changes to the manufacturing process, testing, analytic procedures, acceptance criteria, and associated labeling reflect these changes.

## 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.

| Draft Submitted Labeling | Date submitted |
|---|---|
| 4 oz. grape outer container label | 11/20/2020 |
| 4 oz. grape immediate container (bottle) label | 11/20/2020 |
| 8 oz. grape outer container label | 11/20/2020 |
| 8 oz. grape immediate container (bottle) label | 11/20/2020 |

We remind you to remove the "NEW GRAPE FLAVOR!" flag from the top of the principal display panel 6 months after marketing.

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-11.**" 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.

## 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 Sherry Stewart, PharmD, Senior Regulatory Project Manager, at (301) 796-9618.

Sincerely,

*{See appended electronic signature page}*

Nushin Todd, MD, PhD
Director (Acting)
Division of Nonprescription Drugs I
Office of Nonprescription Drug Products
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/

---

NUSHIN F TODD
03/17/2021 09:29:20 PM