



NDA 209090/S-2

**SUPPLEMENT APPROVAL**

Sanofi-Aventis U.S. LLC  
Attention: Christine Dellanno,  
Category Head - Allergy, Cough & Cold, US Regulatory Affairs CHC  
55 Corporate Drive  
Bridgewater, NJ 08807

Dear Ms. Dellanno:

Please refer to your supplemental new drug application (sNDA) dated and received May 12, 2020, your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children’s Xyzal Allergy 24 HR (levocetirizine dihydrochloride) oral solution, 2.5 mg per 5 mL (0.5 mg per mL).

This “Prior Approval” supplemental new drug application provides for revised labeling to redesign the principal display panel and bottle label.

**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.

<b>Submitted Labeling</b>	<b>Date Submitted</b>
5 fl. oz outer container	10/16/2020
5 fl. oz bottle (immediate container)	10/16/2020

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 209090/S-2.**” 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.<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, call Sherry Stewart, PharmD, Senior Regulatory Project Manager, at (301) 796-9618.

Sincerely,

*{See appended electronic signature page}*

Nushin Todd, MD, PhD  
Deputy Director (Acting)  
Division of Nonprescription Drugs I  
Office of Nonprescription Drugs  
Center for Drug Evaluation and Research

ENCLOSURES:

- 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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11/10/2020 08:27:55 AM