NDA 019835/S-050
NDA 22155/S-027

SUPPLEMENT APPROVAL

Kenvue Brands LLC
Attention: Jennifer Norman, RPh
Director, Regulatory Affairs
7050 Camp Hill Road
Mail Stop 111
Fort Washington, PA 19034-2299

Dear Jennifer Norman:

Please refer to your supplemental new drug applications (sNDA) dated and received on June 4, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Zyrtec Allergy (cetirizine hydrochloride) oral solution, 1 mg per mL and Zyrtec Allergy (cetirizine hydrochloride) tablets, 5 mg and 10 mg.

These "Prior Approval" supplemental new drug applications provide for the following:

NDA 019835/S-050 Zyrtec (cetirizine hydrochloride) tablets, 5 mg and 10 mg

- Revised proprietary name from Zyrtec Hives Relief to Zyrtec Hives
- A new Drug Facts label (DFL) and principal display panel (PDP) for a 30-count bottle and outer carton presentation

NDA 22155/S-027 Zyrtec (cetirizine hydrochloride) oral solution, 1 mg per 1 mL

- Revised proprietary name from Zyrtec Hives Relief to Zyrtec Hives with the labeling descriptor, "Children's"
- A new Drug Facts label (DFL) and principal display panel (PDP) for a 4 fl oz bottle and outer carton presentation.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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.

NDA 19835/S-050 Submitted Draft Labeling	**Date submitted**
30-count outer carton	6/4/2024
30-count bottle peel-back label	8/28/2024
NDA 22155/S-027 Submitted Draft Labeling	**Date submitted**
4 oz outer carton	11/8/2024
4 oz bottle	6/4/2024

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 019835/S-050 and NDA 22155/S-027**." Approval of these submissions 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

[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

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).

If you have any questions, call Tam Dinh, PharmD, Regulatory Project Manager at (240) 402-6284, or email Tam.Dinh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Martha Lenhart, MD, PhD
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Blister Mat 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/

MARTHA K LENHART
11/26/2024 03:45:08 PM