NDA 19835/S-055

SUPPLEMENT APPROVAL

Kenvue Brands LLC
Attention: Carina Fleming
Associate Manager, Regulatory Affairs
1 Kenvue Way
Summit, NJ 07901

Dear Carina Fleming:

Please refer to your supplemental new drug application (sNDA) dated and received December 19, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyrtec Allergy (cetirizine hydrochloride) tablets, 5 mg and 10 mg, and Zyrtec Hives (cetirizine hydrochloride) tablets, 10 mg.

This "Prior Approval" supplemental new drug application provides for a revision to the Drug Facts label to include a warning about new onset pruritus that occurs after discontinuation of cetirizine, in response to the Agency's CBE Supplement Request letter dated July 11, 2025. It also provides for various graphic and text revisions to the labeling.

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.

1. Update the distributor information to Kenvue LLC on the 5 mg 35-count carton and bottle labeling.

2. Correct the editorial error for the 30+10=40 count outer carton label. Incorrect language for the pruritus warning was submitted for this carton, "[bullet] in rare cases, within a few days after stopping long-term daily use of cetirizine you may experience itching. Consult your healthcare provider if this happens." Remove the phrase "a few days" and update the language to state "[bullet] in rare cases, you may experience itching after stopping cetirizine. Consult your healthcare provider if this happens."

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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the labeling listed in the following table with the revisions listed above.

Submitted Draft Label	Date submitted
ZYRTEC 5 mg 15 ct carton	2/6/2026
ZYRTEC 5 mg 1 ct pouch	12/19/2025
ZYRTEC 5 mg 35 ct carton	2/6/2026
ZYRTEC 5 mg 35 ct bottle	12/19/2025
ZYRTEC 10 mg 3 ct Go Pack carton	12/19/2025
ZYRTEC 10 mg 5 ct Go Pack carton	12/19/2025
ZYRTEC 10 mg 14 ct carton	12/19/2025
ZYRTEC 10 mg 30 ct carton	12/19/2025
ZYRTEC 10 mg 30 ct bottle	12/19/2025
ZYRTEC 10 mg 40 ct carton	12/19/2025
ZYRTEC 10 mg 40 ct bottle	12/19/2025
ZYRTEC 10 mg 45 ct carton	2/13/2026
ZYRTEC 10 mg 45 ct bottle	2/13/2026
ZYRTEC 10 mg 50 ct bottle	12/19/2025
ZYRTEC 10 mg 60 ct carton	12/19/2025
ZYRTEC 10 mg 60 ct bottle	12/19/2025
ZYRTEC 10 mg 70 ct bottle	12/19/2025
ZYRTEC 10 mg 75 ct carton	2/13/2026
ZYRTEC 10 mg 75 ct bottle	2/13/2026
ZYRTEC 10 mg 90 ct carton	12/19/2025
ZYRTEC 10 mg 90 ct bottle	12/19/2025
ZYRTEC 10 mg 70+50=120 ct carton	12/19/2025
ZYRTEC 10 mg 50x 1 ct Dispensit carton	12/19/2025
ZYRTEC 10 mg 50x 1 ct Dispensit-Sample carton	12/19/2025
ZYRTEC 10 mg 1 ct pouch	2/13/2026
ZYRTEC 10 mg 1 ct pouch-Sample	12/19/2025
ZYRTEC Hives 10 mg 30 ct carton	12/19/2025
ZYRTEC Hives 10 mg 30 ct bottle	12/19/2025

The FPL should be submitted electronically according to 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 19835/S-055**." 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 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).

If you have any questions, contact Helen Lee, Safety Regulatory Project Manager, at 301-796-6848 or Helen.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Dorothy Chang, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling

[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

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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.

/s/

DOROTHY N CHANG
06/11/2026 03:33:45 PM