NDA 022578/S-014

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
Attention: Jennifer D. Norman, R.Ph.
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 application (sNDA) dated and received on September 29, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Zyrtec Allergy and Zyrtec Allergy (cetirizine hydrochloride) orally disintegrating tablet, 10 mg.

This "Prior Approval" supplemental new drug application provides for:

- a revised principal display panel (PDP) with the use of icons to represent allergy symptoms and a flag added to the PDP for a new look for Zyrtec Allergy and Children's Zyrtec Allergy
- addition of a Dye-Free claim for Zyrtec Allergy
- addition of Dye-Free and Sugar-Free claims for Children's Zyrtec Allergy

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.

We note that you have committed in your electronic communication received on August 7, 2024, that you intend to bold the statement of identity (SOI) on all labeling, as required by 21 CFR 201.61(c).

LABELING

Submit final printed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (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. Bold the statement of identity on the

FPL to be in compliance with 21 CFR 201.61. Remove the "New look Same relief" flag 6 months after marketing.

Submitted Draft Labeling	Date submitted
Children's 12-count outer container	12/14/23
Children's 24-count outer container	12/14/23
Children's 6-count blister card	9/29/23
Zyrtec 24-count outer container	12/14/23
Zyrtec 6-count blister card	9/29/23

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 022578/S-014**." 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.

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 required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as

[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

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, contact Tam Dinh, PharmD, Regulatory Project Manager at 240-402-6284 or Tam.Dinh@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
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
11/15/2024 04:29:53 PM