NDA 019835/S-46

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division
Attention: Jennifer Norman
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 June 2, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyrtec (cetirizine hydrochloride) tablets, 5 mg and 10 mg.

This "Prior Approval" supplemental new drug application provides revisions to the principal display panel for multiple package labels for Zyrtec (cetirizine hydrochloride) tablets,10 mg.

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.

Submitted Draft Labeling	Date
Outer Container Labels	**October 27, 2023**
3 count carton (associated with 1 count pouch)	
5 count carton (associated with 1 count pouch)	
14 count carton (associated with 1 count pouch)	
30 count carton	
40 count carton	
60 count carton	

90 count carton	
120 count carton (associated with 50 count, 70 count bottles)	
Immediate Container Labels	**October 27, 2023**
1 count pouch (associated with 3 count, 5 count, 14 count cartons)	
30 count bottle	
40 count bottle	
50 count bottle (associated with 120 count carton)	
60 count bottle	
70 count bottle (associated with 120 count carton)	
90 count bottle	

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-46**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the "New" claims from the labeling six months after the marketing start date.

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.

[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

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 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 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
Office of New Drug
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
12/01/2023 03:58:50 PM