NDA 19835/S-40

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division
Attention: Jennifer Norman, RPh
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Norman:

Please refer to your supplemental new drug application (sNDA) dated and received February 7, 2019 and your amendments, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyrtec (cetirizine hydrochloride) 5 mg and 10 mg tablets.

This "Prior Approval" supplemental new drug application provides for a new Zyrtec 10 mg tablet 120-count stock-keeping unit consisting of one 50-count and one 70-count bottle together in clamshell packaging with a backer card, and a new Zyrtec 10 mg tablet 90-count stock-keeping unit with clamshell packaging and backer card.

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.

Labeling Recommended for Approval

Item	Receipt Date
90-count outer container (card)	07/17/2019
90-count immediate container (bottle)	07/17/2019
120-count outer container (card)	07/17/2019

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 19835/S-40**." 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.

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 Sherry Stewart, Regulatory Project Manager, at 301-796-9618.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
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/

THERESA M MICHELE
08/07/2019 04:16:12 PM