



NDA 20958/S-029

## **SUPPLEMENT APPROVAL**

Johnson & Johnson Consumer Inc.  
McNeil Consumer Healthcare Division  
Attention: Cindy R. Abraham, RAC  
7050 Camp Hill Road  
Mail Stop 111  
Fort Washington, PA 19034

Dear Ms. Abraham:

Please refer to your supplemental new drug application (sNDA) dated and received December 21, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid Complete (famotidine 10 mg, calcium carbonate 800 mg, magnesium hydroxide 165 mg) chewable tablet.

This “Changes Being Effectuated” sNDA provides for addition of FDA-requested safety information to the Drug Facts Labeling (DFL) under the “Ask a doctor before use if you have” and “Ask a doctor or pharmacist before use if you are taking” Warnings subheadings to three labels (i.e., 4- and 8- count cartons, and 1-count immediate container (pouch)).

This supplement also provides for the following:

- Revision to the declaration of net quantity of contents so that it is distinct from the flavor statement (“Berry Flavor,” “Cool Mint Flavor,” or “Tropical Fruit Flavor”)
- Addition of the strength of each active ingredient to the statement of identity
- Addition of the “Tips for Managing Heartburn” to the outer cartons (i.e., 4- and 8-count)

### **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 1-count immediate container (pouch) and 4- and 8-count carton labels submitted on March 21, 2019 and Drug Facts font and format specifications submitted on April 3, 2019; and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20958/S-029.**” 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.<sup>2</sup> 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 CAPT Alina Salvatore, Regulatory Project Manager, at (240) 402-0379

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

### **ENCLOSURE(S):**

- Carton and Container Labeling

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<sup>1</sup> 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>.

<sup>2</sup> <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.**  
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/s/  
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THERESA M MICHELE  
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