



NDA 021524/S-020

**SUPPLEMENT APPROVAL**

Professional Disposables International, Inc.  
Attention: Hemangini K. Patel, MD, MSJ  
Director, Regulatory Affairs  
Two Nice-Pak Park  
Orangeburg, NY 10962

Dear Dr. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 24, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevantics<sup>®</sup> (3.15% w/v chlorhexidine gluconate, 70% v/v isopropyl alcohol), swab.

This “Changes Being Effected” supplemental new drug application revises the Prevantics<sup>®</sup> Swab labeled concentration to reflect the product’s nominal concentration of the active ingredient chlorhexidine gluconate.

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 agreed-upon labeling text and with the minor editorial revisions listed below.

For the Prevantics<sup>®</sup> Swab 100-count outer carton Drug Facts labeling:

Under the “**Warnings**” heading, revise the letter “**f**” to upper case in the “**for external use only**” and the flammability statements to read: “**For external use only**” and “**Flammable, keep away from fire or flame**” according to 21 CFR 201.66(c)(5)(i) and 21 CFR 201.66(c)(5)(ii)(C).

**LABELING**

Submit final printed labeling (FPL) for the Prevantics<sup>®</sup> Swab product line as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling submitted on November 12, 2018, include the minor editorial revisions listed above 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 titled Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical

Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4). For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 021524/S-020**”. 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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 Celia Peacock, Senior Regulatory Project Manager at (301) 796-4154.

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, Container, and Package Insert Labeling

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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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