DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021524/S-012

SUPPLEMENT APPROVAL

Professional Disposables International, Inc.
Attention: Robert Sheroff
VP of Quality Assurance & Regulatory Affairs
Two Nice-Pak Park
Orangeburg, NY 10962

Dear Mr. Sheroff:

Please refer to your Supplemental New Drug Application (sNDA) dated December 18, 2012, received December 19, 2012, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevantics™ Swab, Prevantics™ Swabstick, & Prevantics™ Maxi Swabstick, (3.15% w/v chlorhexidine gluconate, 70% v/v isopropyl alcohol), swabs.

We acknowledge receipt of your amendment dated August 12, 2017, which constituted a complete response to our October 8, 2013, action letter.

This "Prior Approval" supplemental new drug application provides for Drug Facts labeling changes under the ***Directions*** heading to revise the stated preparation time of a dry site from 120 seconds scrubbing and 90 seconds drying to 30 seconds scrubbing and 30 seconds drying. In addition, it provides for a Drug Facts labeling ***Allergy alert*** warning as requested in a February 2, 2017, supplement request letter.

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.

LABELING

Submit final printed labeling (FPL), with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the following labeling submitted on December 28, 2017:

- Prevantics® Swabstick 50-count outer carton
- Prevantics® Swabstick 500-count secondary outer carton (ten 50-count cartons)
- Prevantics® Swabstick 500-count outer carton
- Prevantics® Swabstick immediate container (foil pouch)
- Prevantics® Swabstick package insert (500-count outer carton)

- Prevantics® Swabstick bulk immediate container (foil pouch)
- Prevantics® Maxi Swabstick 30-count outer carton
- Prevantics® Maxi Swabstick 300-count secondary outer carton (ten 30-count cartons)
- Prevantics® Maxi Swabstick 300-count outer carton
- Prevantics® Maxi Swabstick immediate container (foil pouch)
- Prevantics® Maxi Swabstick package insert (300-count outer carton)
- Prevantics® Maxi Swabstick bulk immediate container (foil pouch)
- Prevantics® Compact Swabstick 500-count outer carton
- Prevantics® Compact Swabstick package insert (500-count carton)
- Prevantics® Compact Swabstick bulk immediate container (foil pouch)

Submit FPL 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 (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021524/S-012**." 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,

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
02/14/2018