DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021524/S-017

SUPPLEMENT APPROVAL

Professional Disposables International, Inc.
Attention: Dawn Rubel
Vice President, Quality and Regulatory Affairs
Two Nice-Pak Park
Orangeburg, NY 10962

Dear Ms. Rubel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 9, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevantics® (3.15% w/v chlorhexidine gluconate (w/v) and 70% v/v isopropyl alcohol) swab, swabstick, and maxi swabstick.

This "Changes Being Effected" supplemental new drug application provides for the addition of "Allergy alert" warning and related changes in accordance with the Agency's "Changes Being Effected" (CBE-0) Request Letter dated February 2, 2017.

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 incorporation of the minor editorial changes noted below:

1. For the products listed below:

    - Prevantics® Swab 100-count outer carton
    - Prevantics® Swab 1,000-count secondary outer carton (contains ten 100-count cartons)
    - Prevantics® Swab 3,000-count outer carton
    - Prevantics® Swab package insert (3,000-count carton)
    - Prevantics® Swabstick 500-count outer carton
    - Prevantics® Maxi Swabstick 30-count outer carton
    - Prevantics® Maxi Swabstick 300-count secondary carton (contains ten 30-count cartons)
    - Prevantics® Maxi Swabstick 300-count outer carton
    - Prevantics® Compact Swabstick 500-count outer carton
    - Prevantics® Swabstick package insert (front and back panels) (500-count outer carton)

Under the "**Allergy alert:**" subheading, reformat the bulleted statements: "[bullet] wheezing/difficulty breathing [bullet] shock [bullet] facial swelling [bullet] hives [bullet] rash" so that the bulleted statements placed below a horizontal line with more than one bulleted statement, are vertically aligned with those of the previous line, according to 21 CFR 201.66(d)(4): "...If more than one bulleted statement is placed on the same horizontal line, the end of one bulleted statement shall be separated from the beginning of the next bulleted statement by at least two square "ems"[1] and the complete additional bulleted statement(s) shall not continue to the next line of text. Additional bulleted statements appearing on each subsequent horizontal line of text under a heading or subheading shall be vertically aligned."

2. For the products listed below:

   - Prevantics® Swabstick 500-count outer carton
   - Prevantics® Swabstick package insert (500-count outer carton)
   - Prevantics® Compact Swabstick 500-count outer carton

   Under the "Allergy alert:" subheading, the "If an allergic reaction occurs, stop use…" statement should not immediately follow the bulleted statements "[bullet] wheezing/difficulty breathing [bullet] shock [bullet] facial swelling [bullet] hives [bullet] rash" on the same line horizontal line. Therefore, move the "If an allergic reaction occurs, stop use..." statement to the next line to be consistent with the recommendation in the Changes Being Effected supplement letter.

3. For the products listed below:

   - Prevantics® Swab 100-count outer carton
   - Prevantics® Swab 1,000-count secondary outer carton (ten 100-count cartons)
   - Prevantics® Swab 3,000-count outer carton
   - Prevantics® Swab package insert (3,000-count outer carton)
   - 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 package insert 500-count outer carton
   - 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 package insert (300-count outer carton)
   - Prevantics® Reduced Length Swabstick 500-count outer carton
   - Prevantics® Reduced Length Swabstick package insert(500-count outer carton)

[1] *two squares of the size of the letter "M"*

a. Under the Drug Facts labeling "**Warnings**" heading, reformat the allergic reaction warning subheading by changing the first letter in "Alert" from upper case to lower case and inserting a colon after the "t" to appear as: "**Allergy alert:**" as required under 21 CFR 201.66(c)(5)(ii)(B) and (d)(1).
b. Revise the first letter of the bulleted statements under the **"Allergy alert:"** subheading of the "**Warnings"** section; "[bullet]Wheezing/difficulty breathing [bullet] Shock [bullet] Facial swelling [bullet] Hives [bullet] Rash" from upper case to lower case.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the Prevantics (3.15% w/v chlorhexidine gluconate (w/v) and 70% v/v isopropyl alcohol) swab, swabstick, and maxi swabstick labeling submitted August 3, 2017, after incorporating the changes specified above. The final printed labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling 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-017**." 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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
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/

VALERIE S PRATT
09/07/2017