DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021524/S-015 **SUPPLEMENT APPROVAL**

Professional Disposables International, Inc.
Attention: Anindita Deogharia
Senior Manager, Regulatory Affairs
Two Nice-Pak Park
Orangeburg, NY 10962

Dear Ms. Deogharia:

Please refer to your Supplemental New Drug Application (sNDA) dated January 31, 2014, received February 4, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevantics™ (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol) swab, swabstick, and maxi swabstick.

We acknowledge receipt of your amendments dated May 29, June 6, and June 17, 2014.

This "Changes Being Effected" sNDA provides for the addition of a sterility statement.

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) 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 May 29, 2014

1. Prevantics™ Swab immediate container
2. Prevantics™ Swab immediate container for 3,000-count carton
3. Prevantics™ Swabstick immediate container
4. Prevantics™ Swabstick immediate container for 500-count carton
5. Prevantics™ Maxi Swabstick immediate container
6. Prevantics™ Maxi Swabstick immediate container for 300-count carton
7. Prevantics™ Compact Swabstick immediate container

Labeling submitted on June 17, 2014

1. Prevantics™ Swab 100-Count Outer Carton
2. Prevantics™ Swab 100 secondary packaging that holds ten 100-count cartons
3. Prevantics™ Swab 100 outer carton for the 3,000-count
4. Prevantics™ Swab package insert for the 3,000-count
5. Prevantics™ Swabstick 50-count outer carton
6. Prevantics™ Swabstick secondary packaging that holds ten 50-count cartons
7. Prevantics™ Swabstick outer carton for the 500-count
8. Prevantics™ Swabstick Package Insert for the 500-count
9. Prevantics™ Maxi Swabstick 30-count outer carton
10. Prevantics™ Maxi Swabstick secondary packaging that holds ten 30-count cartons
11. Prevantics™ Maxi Swabstick outer carton for the 300-count
12. Prevantics™ Maxi Swabstick package insert for the 300-count
13. Prevantics™ Compact Swabstick outer carton for the 500-count
14. Prevantics™ Compact Swabstick package insert for the 500-count

Submit labeling 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021524/S-015**.

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, Regulatory Project Manager at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
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
07/25/2014