DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021524/S-011

SUPPLEMENT APPROVAL

Professional Disposables International, Inc.
Attention: Elizabeth Ernst
Director of Regulatory and Medical Affairs
Two Nice-Pak Park
Orangeburg, NY 10962-1376

Dear Ms. Ernst:

Please refer to your Supplemental New Drug Application (sNDA) dated November 18, 2011, received, November 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

Chlorascrub™ Swab (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol)
Chlorascrub™ Swabstick (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol)
Chlorascrub™ Maxi Swabstick (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol)
Chlorascrub™ Reduced Length Swabstick (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol)

We acknowledge receipt of your amendments dated January 20, 2012, and April 11, 2012.

This "Changes Being Effected" supplemental new drug application provides for changes in the Drug Facts labeling to add directions for use in infants.

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 following minor editorial revisions:

For all the submitted *Drug Facts* labeling, move the infant use warning statement "■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns." to be the first bulleted statement in ***Directions***.

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 (FPL) must be identical to the enclosed labeling listed below:

Labeling submitted November 18, 2012

1. Swab immediate container (foil pouch)
2. Swab secondary packaging that holds ten 100-count cartons
3. Swab 3,000-count outer carton
4. Swab immediate container (foil pouch) for 3,000-count carton
5. Swab package insert (front and back panels) for 3,000-count carton
6. Swabstick immediate container (foil pouch)
7. Swabstick secondary packaging that holds ten 50-count cartons
8. Swabstick 500-count outer carton
9. Swabstick immediate container (foil pouch) for 500-count carton
10. Maxi Swabstick 30-count outer carton
11. Maxi Swabstick immediate container (foil pouch)
12. Maxi Swabstick outer carton for the 300-count
13. Maxi Swabstick immediate container (foil pouch) for 300-count carton
14. Reduced Length Swabstick 500-count outer carton
15. Reduced Length Swabstick immediate container (foil pouch) for 500-count carton

Labeling submitted April 11, 2012

16. Swab 100-count outer carton
17. Swabstick 50-count outer carton
18. Swabstick package insert (front and back panels) for 500-count carton
19. Maxi Swabstick secondary packaging that holds ten 30-count cartons
20. Maxi Swabstick package insert (front and back panels) for 300-count carton
21. Reduced Length Swabstick package insert (front and back panels) for 500-count carton

This FPL 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 – 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-011**." 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}

Joel Schiffenbauer, M.D.
Deputy 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/

JOEL SCHIFFENBAUER
05/17/2012