NDA 021524/S-024

SUPPLEMENT APPROVAL

Professional Disposables International, Inc.
Attention: Kathy O'Sullivan, MS, MSJ, RAC
Senior Director Regulatory Affairs
400 Chestnut Ridge Road
Woodcliff Lake, New Jersey 07677-7604

Dear Ms. O'Sullivan:

Please refer to your supplemental new drug application (sNDA) dated and received April 15, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevantics (chlorhexidine gluconate, 3.15% and isopropyl alcohol, 70%) maxi swabstick.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

- To change to a single coverage area (8.4 in. x 8.4 in.) for both dry and moist sites and revise the statement on the label from "Maximum treatment area for one maxi swabstick is approximately: dry site: 7 by 7 inches (18 by 18 cm) or moist site: 3 by 7.5 inches (7.5 by 19 cm)" to "Maximum treatment area for one maxi swabstick is approximately: 8.4 in. x 8.4 in. (21.3 by 21.3 cm)"
- To revise the statement on the label from "Do not use with electrocautery procedures" to "Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)."
- Revisions to Drug Facts Warnings, Drug Facts Directions, and Boxed Flammability Warning Labels and symbols to align with other similarly approved products
- Removal of (b) (4) from shipper labels

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66),

where applicable.

Submitted Labeling	Date Submitted
Prevantics Maxi Swabstick immediate container (foil pouch)	June 18, 2021
Prevantics Maxi Swabstick 30-count outer carton	June 18, 2021
Prevantics Maxi Swabstick bulk immediate container (foil pouch)	June 18, 2021
Prevantics Maxi Swabstick bulk package insert (bulk 300-count outer carton)	June 18, 2021
Prevantics Maxi Swabstick 300-count secondary outer carton (ten 30-count cartons)	July 15, 2021
Prevantics Maxi Swabstick bulk 300-count outer carton	July 15, 2021

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021524/S-024**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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, contact Michael Boblitz, PharmD, Regulatory Project Manager at Michael.Boblitz@fda.hhs.gov or (301) 837-7651.

Sincerely,

{See appended electronic signature page}

Francis E. Becker, MD, FACP
Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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.

/s/

FRANCIS E BECKER
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