DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-524/S-003

Nice-Pak Products, Inc.
Attention: Bob Reichman
VP Quality & Production
U.S. Agent for Les Enterprises SoluMed, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962

Dear Mr. Reichman:

Please refer to your supplemental new drug application dated August 9, 2006, received August 25, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Chlorascrub™ Swab [chlorhexidine gluconate (3.15%)* and isopropyl alcohol (70%) swab] *equivalent to 167 mg of chlorhexidine gluconate per pouch.

We acknowledge receipt of your submissions dated December 22, 2006, January 18, 2007, and February 7, 2007.

Your submission of February 7, 2007 constituted a complete response to our December 21, 2006 action letter.

This supplemental application proposes to add an alternate tear open web foil [(b)(4)], alternate tear opening labeling, and an ethylene oxide (ETO) sterilization monograph for kit packers in order for the Chlorascrub Swab to be incorporated into medical kits.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

Shipping Label

1. No separate Principal Display Panel (PDP) was provided for the outermost container. Therefore, we consider the area above the ***Drug Facts*** to be the PDP and, as such, must meet the requirements for a PDP. As required by 21 C.F.R. § 201.62(e), the net contents statement must appear in the lower 30 percent of the PDP. Reposition the net contents statement so that it is in the lower 30 percent of the PDP.

2. Include the amount of solution in each swab as part of the net contents statements. This is consistent with the previous approved labeling. The net contents should be revised to read as follows:

Contains: 3000 Individual Swabs, 0.034 fl. oz. (1 mL) Each

The final printed labeling (FPL) must be identical to, and include the revisions listed, the submitted labeling (package insert submitted February 7, 2007, and the shipping label (containing the Principal Display Panel and Drug Facts) submitted February 7, 2007); and must be formatted in accordance with the requirements of 21 C.F.R. § 201.66 where applicable. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-524/S-003**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit one copy of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print.

Please submit one market package of the drug product when it is available.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We further remind you of our previous discussions concerning the promotion, marketing, and distribution of Chlorascrub™ Swab to device kit manufacturers and assemblers. Many of those firms prepare institutional, hospital, and surgical kits to meet the exact specifications of the purchaser. Those specifications often include uses for which Chlorascrub™ Swab has not been approved. As discussed, you may not promote, market, or distribute Chlorascrub™ Swab for any unapproved uses. To do so would cause Chlorascrub™ Swab to be misbranded and an unapproved new drug. We recommend that you review the meaning of "intended uses" under 21 C.F.R. § 201.128.

If you have any questions, call Laura E. Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

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