CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-524

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-524

Nice-Pak Products, Inc.
U.S. Agent for Les Entreprises SoluMed, Inc.
Attention: Bob Reichman
Vice President Quality & Production
Two Nice-Pak Park
Orangeburg, New York 10962

Dear Mr. Reichman:

Please refer to your new drug application (NDA) dated July 26, 2004, received August 5, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for:

Chlorascrub™ Swab [Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Chlorascrub™ Swabstick [Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Chlorascrub™ Maxi Swabstick [Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

We acknowledge receipt of your submissions dated May 28 (chemistry presubmission), August 19, November 5, and 10, 2004; February 10, and 15, March 9, and 30, April 15, 20, and 21, and May 26, June 1, and 2, 2005.

This new drug application provides for the use of Chlorascrub™ Swab, Chlorascrub™ Swabstick and Chlorascrub™ Maxi Swabstick [Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab] for the following indications:

- Patient preoperative skin preparation [Chlorascrub™ Swabstick and Chlorascrub™ Maxi Swabstick]
- Patient pre-injection preparation [Chlorascrub™ Swab, Chlorascrub™ Swabstick, and Chlorascrub™ Maxi Swabstick]

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.

The final printed labeling (FPL) must be identical to the labeling (immediate container label and outer container and carton labels) submitted June 2, 2005 (see attached), and must be in the "Drug Facts" format in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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 NDA 21-524.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for children less than 2 months of age, as well as, for premature or low birth weight infants, and infants receiving phototherapy due to the potential for irritation and enhanced absorption.

You do not have any pediatric post-marketing study commitments.

In addition, we request that you submit a copy of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send the copies to the Division of Anti-Infective and Ophthalmology Products, HFD-520.

Please submit one market package of each of the drug product presentations when they are available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

Oversight of this application is being transferred to the Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products. If you have any questions, call Tia Frazier R.N., Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Office of New Drugs
Center for Drug Evaluation and Research

Enclosure – Labeling (11 pages)

cc: Les Entreprises Solumed, Inc.
Attention: Anna Mallozzi, B. Chem. Eng.
Regulatory Affairs
2109 Le Chatelier
Laval (QUEBEC)
H7L 5B3 CANADA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lillian Gavrilovich
6/3/05 10:51:07 AM
Signing for Dr. Janice Soreth.

Curtis Rosebraugh
6/3/05 11:24:50 AM