DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-481/S-007

United Guardian, Inc.
Attention: Kristen J. Nantista
Quality Assurance Manager
230 Marcus Blvd., P.O. Box 18050
Hauppauge, NY 11788

Dear Ms. Nantista:

Please refer to your supplemental new drug application dated December 12, 2006, received January 3, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renacidin® (citric acid (anhydrous), glucono delta-lactone, magnesium carbonate, benzoic acid) Irrigation, 10%.

We acknowledge receipt of your submissions dated April 19 and 27, 2007.

This "Prior Approval" supplemental new drug application provides for an alternate manufacturing facility at ---------- -- -------- ---------. The changes for the manufacturing facility are the following:

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We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the labeling text submitted on December 12, 2007 and with the following change to the Immediate container label.

- Please change the size of the established name in the Immediate Container label to half the size of the trade name to comply with 21 CFR 201.10(g)(2).

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the labeling submitted on December 12, 2006. These revisions are terms of the approval of this application.

Please submit the final printed carton and container labels electronically that is identical to, except for including the revisions listed/indicated, the submitted immediate container labels. Alternatively, you may submit 12 paper copies of the final printed carton and container labels as soon as they are

available but no more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 19-481/S-007."** Approval of this submission by FDA is not required before the labeling is used.

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).

If you have any questions, call Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Eric Duffy

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