



Kenneth H. Globus  
President  
United-Guardian, Inc.  
230 Marcus Blvd, P.O. Box 18050  
Hauppauge, NY 11788

**RE: NDA 19481**  
RENACIDIN® (CITRIC ACID, GLUCONO DELTA-LACTONE, AND MAGNESIUM  
CARBONATE) Irrigation Solution  
MA 7

## WARNING LETTER

Dear Mr. Globus:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the professional email (e-mail) for RENACIDIN® (CITRIC ACID, GLUCONO DELTA-LACTONE, AND MAGNESIUM CARBONATE) Irrigation Solution (Renacidin) submitted by United-Guardian, Inc. (United-Guardian) under cover of Form FDA 2253. The e-mail makes false or misleading claims and/or representations with regard to the risks and benefits associated with Renacidin. Thus, the e-mail misbrands Renacidin within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). See 21 CFR 202.1(e)(5). These violations are concerning from a public health perspective because they create a misleading impression about the safety of Renacidin.

### Background

Below are the indication and summary of the most serious and most common risks associated with the use of Renacidin.<sup>1</sup>

According to the FDA-approved product labeling (PI), Renacidin is indicated for dissolution of bladder calculi of the struvite or apatite variety by local intermittent irrigation through a urethral catheter or cystostomy tube as an alternative or adjunct to surgical procedures. Renacidin is also indicated for use as an intermittent irrigating solution to prevent encrustations of indwelling urethral catheters and cystostomy tubes.

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<sup>1</sup> This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

Renacidin is contraindicated in the presence of demonstrable urinary tract extravasation. The PI for Renacidin contains warnings regarding fever, urinary tract infection, persistent flank pain, elevated serum creatinine, complications from inadequate aseptic technique, sepsis, hypermagnesemia and precautions regarding patency of the urethral catheter or cystostomy tube, vesicoureteral reflux, laboratory monitoring and concomitant use of medications containing magnesium. The most common adverse reactions observed with Renacidin were “bladder irritability” and chemical cystitis.

### **False or Misleading Risk Presentation**

Promotional materials misbrand a drug if they are false or misleading with respect to risk. The determination of whether promotional materials are misleading includes, among other things, not only representations made or suggested in promotional materials, but also failure to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the materials.

The e-mail contains multiple claims and/or representations about Renacidin; however, it fails to communicate **any** risk information. We note the statement, “CLICK HERE for complete prescribing information[,]” is included in the e-mail. However, this statement does not mitigate the omission of the risk information from the e-mail. By omitting the risks associated with Renacidin, the e-mail fails to provide material information about the consequences that may result from the use of the drug and creates a misleading impression about the drug’s safety.

### **False or Misleading Benefit Presentation**

The e-mail includes the following claims regarding benefits of Renacidin:

- “Simplifies long-term catheter care”
- “Easy 30 mL dosing and delivery”

No references are cited to support these general claims that Renacidin simplifies long-term care of in-dwelling catheters or is easy to use, and we are not aware of supporting evidence. In addition, the unsupported and thus misleading assertion that Renacidin has “Easy 30 ml dosing and delivery” is exacerbated by the failure of the e-mail to reveal specific information from the approved physician labeling about how the drug should be dosed and administered. Specifically, the DOSAGE AND ADMINISTRATION section of the PI states, “Instill 30 mL (one container) of Renacidin into the urethral catheter or cystostomy tube. Clamp the urethral catheter or cystostomy tube for 10 minutes. Remove the clamp and drain the bladder. Repeat the instillation procedure 3 times a day” (emphasis added). This omission of material information further exacerbates the misleading characterization of dosing and delivery in the e-mail.

## Conclusion and Requested Action

For the reasons discussed above, the e-mail misbrands Renacidin within the meaning of the FD&C Act, and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). See 21 CFR 202.1(e)(5).

OPDP requests that United-Guardian immediately cease misbranding Renacidin and/or cease introducing the misbranded drug into interstate commerce. Please submit a written response to this letter on or before December 28, 2016, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Renacidin that contain presentations such as those described above, and explaining your plan for discontinuing use of such materials, or, in the alternative, for ceasing distribution of Renacidin. Because the violations described above are serious, we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience(s) that received the violative promotional materials. In order to clearly identify the violative promotional piece(s) and/or activity and focus on the corrective message(s), OPDP recommends that corrective piece(s) include a description of the violative promotional piece(s) and/or activity, include a summary of the violative message(s), provide information to correct each of the violative message(s), and be free of promotional claims and presentations. To the extent possible, corrective messaging should be distributed using the same media, and generally for the same duration of time and with the same frequency that the violative promotional material was disseminated.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Amundson Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile at (301) 847-8444. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA 7 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Warning Letter. OPDP reminds you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that Renacidin complies with each applicable requirement of the FD&C Act and FDA implementing regulations.

Failure to correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

{See appended electronic signature page}

Robert Dean  
Director, Division of Advertising and  
Promotion Review 2  
Office of Prescription Drug Promotion

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT T DEAN  
12/13/2016