DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-151/S-025

Vatring Pharmaceuticals, Inc.
Attention: Charles Patrick Sutphin
Chairman and CEO
1121 Virginia Avenue
Bluefield, VA 24605

Dear Mr. Sutphin:

Please refer to your supplemental new drug application dated November 12, 2007, received November 16, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Urex™ (methenamine hippurate) 1 gram, oral tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to include the language required in the final rule, **Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use** (68 FR 6062, February 6, 2003), and minor clarifications adding information on the strains of bacteria used for Ames testing.

We completed our review of this application and 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 enclosed labeling submitted on November 12, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 16-151/S-025**." 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 J. Christopher Davi, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}
Katherine A. Laessig, MD
Deputy Division Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on November 12, 2007

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

/s/

Kathrine Laessig
3/11/2008 11:22:03 AM