DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-555/S-009

Enturia, Inc.
Attention: Linda McBride, R.Ph.
Senior Director, Regulatory Affairs
11400 Tomahawk Creek Parkway, Suite 310
Leawood, Kansas 66211

Dear Ms. McBride:

Please refer to your supplemental new drug application dated April 9, 2007, received April 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (2% chlorhexidine gluconate (w/v) topical solution).

This supplemental application proposes to revise the labeled storage statement on the carton label from "store between 20-25ºC (68-77ºF)" to "store between 15-30ºC (59-86ºF)."

We have completed our review of this application. This application 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 agreed enclosed labeling text (outer carton) submitted April 9, 2007 and must be formatted in accordance with the requirements of 21 CFR 201.66. We remind you that all previous revisions as, reflected in the most recently approved labeling, must be included for all other labeling components.

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 21-555/S-009**." 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Robin Anderson, Regulatory Project Manager, at (301) 796-0534.

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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