DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-018

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 December 14, 2006, received December 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (2% chlorhexidine gluconate (w/v) topical solution) 3-mL applicator with tint applicator containing FD&C Green #3 dye.

This supplemental application proposes to revise the labeling of the 3-mL ChloraPrep® with tint applicator containing FD&C Green #3 dye with revised warning statements in relation to use of the product with electrocautery procedures as approved in Supplement 012 on December 8, 2006 for other packaging configurations.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (outer carton with Drug Facts, barrel label, and lidding with Drug Facts submitted on December 14, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

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 20-832/S-018"**. 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 Laura E. Shay, Regulatory Project Manager, at (301) 796-0994.

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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