DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-695/S-006

Oscient Pharmaceuticals
Attention: Kristine Riley
Senior Associate, Regulatory Affairs
1000 Winter Street, Suite 2200
Waltham, MA 02451

Dear Ms. Riley:

Please refer to your supplemental new drug application dated March 28, 2008, received March 31, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Antara (fenofibrate) Capsules, 43 mg, 130 mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the "Other Considerations" subsection of the WARNINGS section and to the PRECAUTIONS sections of the package insert to included information regarding the FIELD study requested in our letter dated March 10, 2008.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 28, 2008.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Eric Colman
6/3/2008 11:32:22 AM
Eric Colman for Mary Parks