DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-397/S-021
NDA 21-447/S-002

Acorda Therapeutics
Attention: Brian A Walter, PhD
Senior Director, Regulatory Affairs and Quality Assurance
15 Skyline Drive
Hawthorne, NY 10532

Dear Dr. Walter:

Please refer to your supplemental new drug applications dated September 2, 2004 and March 23, 2005, received September 16, 2004 and March 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zanaflex (tizanidine) tablets and capsules.

We acknowledge receipt of your submissions dated April 21, 2005.

These supplemental new drug applications provide for the addition of language in product labeling describing clinically significant drug interactions between tizanidine and fluvoxamine/ciproflaxacin.

We completed our review of these applications, as amended. These applications are 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 (text for the package insert, text for the patient package insert) and/or submitted

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 these submissions "**FPL for approved supplement NDA 20-397/S-021 and NDA 21-447/S-002**." Approval of these submissions by FDA is not required before the labeling is used.

Finally, we request that you issue a "Dear Health Care Professional" letter communicating this important information about this drug product. We request that you submit a copy of the letter to this NDA for our comment prior to issuing the letter.

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 Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
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/

Russell Katz

7/28/2006 04:14:28 PM