DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21447/S-011
NDA 20397/S-026

SUPPLEMENT APPROVAL

Acorda Therapeutics
Attention: Susi L. Antoniuk
Director, Regulatory Affairs
420 Saw Mill River Road
Ardsley, NY 10502

Dear Ms. Antoniuk:

Please refer to your Supplemental New Drug Applications (sNDA) dated June 21, 2012, received June 21, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zanaflex® tablets 4 mg and Zanaflex® capsules 2 mg, 4 mg, and 6 mg.

We acknowledge receipt of your 2013 amendments for NDA 21447/S-011 dated January 18, April 1, September 20, and October 11. We also acknowledge receipt of your 2013 amendments for NDA 20397/S-026 dated April 1, September 20, and October 11.

These "Prior Approval" supplemental new drug applications provide for conversion of the package insert in accordance with 21CFR201.56(d) and 201.57. These supplemental new drug applications also provide for revisions to the labeling for Zanaflex® tablets and Zanaflex® capsules.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, contact Taura Holmes, PharmD, Regulatory Project Manager, via email or telephone at taura.holmes@fda.hhs.gov or (301) 796-1932.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Acting Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

ERIC P BASTINGS
11/07/2013