DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22250 / S-008

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGMENT

Acorda Therapeutics
Attention: William Pfister, PhD
Senior Director Development Regulatory Affairs
420 Saw Mill River Road
Ardsley, NY 10502

Dear Dr. Pfister:

Please refer to your Supplemental New Drug Application (sNDA) dated December 18, 2012, received December 18, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ampyra (dalfampridine) tablets.

We also acknowledge receipt of your amendments dated December 21, 2012 and May 17, 2013.

We acknowledge your risk evaluation and mitigation strategy (REMS) assessment dated January 18, 2013. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

This supplemental new drug application proposes to eliminate the requirement for the approved Ampyra (dalfampridine) REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Ampyra (dalfampridine) was originally approved on January 22, 2010, and the most recent REMS modification was approved on July 20, 2012. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA eliminate the requirement for a REMS for Ampyra (dalfampridine).

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that the communication plan is no longer necessary to ensure that the benefits of the drug outweigh the risks. Therefore, we agree with your proposal, and a REMS for Ampyra (dalfampridine) is no longer required.

In your proposed REMS modification submitted on December 18, 2012, you provided for revised letters to prescribers and pharmacists to advise them of new safety information regarding anaphylaxis and other severe allergic reactions. We do not consider it necessary for information

about this recently characterized risk to be communicated as a part of a REMS, but you may voluntarily send these letters outside of the REMS. We have a few suggestions for revision; the two letters with our suggested revisions are attached to this letter. Please contact us if you have any questions about our suggested revisions.

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, call Nicole Bradley, PharmD, Regulatory Project Manager, at (301) 796-1930.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center of Drug Evaluation and Research

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

/s/

RUSSELL G KATZ
06/18/2013