DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202080/S-003

SUPPLEMENT APPROVAL

Acura Pharmaceuticals, Inc.
616 N. North Court
Suite 120
Palatine, IL 60067

Attention: Anne McKay
Regulatory

Dear Ms. McKay:

Please refer to your Supplemental New Drug Application (sNDA) dated July 22, 2014, received July 24, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OXAYDO (oxycodone hydrochloride immediate-release tablets).

We acknowledge receipt of your amendments dated July 29 and September 18, 2014, and January 9, 2015.

This "Changes Being Effected" supplemental new drug application provides for inclusion of the new tradename OXAYDO on the product container labels.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling.

We acknowledge your January 9, 2015, submission containing final printed carton and container labels.

We remind you of your January 9, 2015, commitment to submit the approved package insert in your next annual report with the only change being the substitution of the old trade name, OXECTA, with the new tradename, OXAYDO. In addition, in the DOSAGE AND ADMINISTRATION section of the HIGHLIGHTS and FULL PRESCRIBING INFORMATION, revise the product strength from "5" to "5 mg" to add the unit of measure. Besides the name change and the addition of the unit of measure as requested above, no other changes should be made to the approved package insert.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Lisa Basham, Senior Regulatory Health Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Acting Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

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

/s/

SHARON H HERTZ
01/26/2015