DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011011/S-079

SUPPLEMENT APPROVAL

Auxilium Pharmaceuticals, LLC
1400 Atwater Drive
Malvern, PA 19355

Attention: Erin Abdallah
Associate Director, Regulatory Affairs Liaison

Dear Ms. Abdallah:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 18, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Robaxin and Robaxin-750 (methocarbamol) tablets.

This Prior Approval supplemental new drug application provides for the following change for Robaxin: revise the 500 mg and 750 mg strength bottle labels to replace specific dosage instructions with "See package insert for full prescribing information."

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and/or carton and container labeling submitted on October 18, 2018, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2018, Revision 5)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 011011/S-079**." Approval of this submission by FDA is not required before the labeling is used.

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 Eva Yuan, Regulatory Project Manager, at 240-402-2476.

Sincerely,

{See appended electronic signature page}

Joshua Lloyd, MD
Deputy Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOSHUA M LLOYD
03/01/2019 11:00:19 AM