DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022195
NDA 022207

NOTIFICATION OF NON-COMPLIANCE WITH PREA

Roxane Laboratories, Inc.
Attention: Jerald Andry, Pharm.D., M.S.
Director, Clinical Development
1809 Wilson Road
Columbus, OH 43228

Dear Dr. Andry:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for morphine sulfate solution and tablets, which were approved on March 17, 2008.

The Agency has determined that you have failed to fulfill the postmarketing requirement (PMR 204-3) of the Pediatric Research Equity Act (PREA) for this application, which was deferred until October 1, 2012. Therefore, we are hereby notifying you that you are not in compliance with federal law.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

In accordance with FDASIA, FDA will post this letter and your response on the website located at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDAs with a cross-reference letter to the IND to which your protocol has been submitted. In addition, send a copy of the cover letter to CDER's Division of Pediatric and Maternal Health.

If you have any questions, call Christopher Hilfiger, Regulatory Project Manager, at (301) 796-4131.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for 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/

JUDITH A RACOOSIN on behalf of SHARON H HERTZ
02/05/2016