NDA 200534
NDA 200535

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Genius Lifesciences Inc.
514 North 12th Street
Allentown, PA 18102

Attention: William Reightler
Vice President of Regulatory Affairs

Dear William Reightler:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for the following, which were approved on October 20, 2010:

NDA Number	Product Name
200534	Oxycodone hydrochloride capsules
200535	Oxycodone hydrochloride oral solution

The Agency has determined that you have failed to meet the postmarketing requirements (PMRs) of the Pediatric Research Equity Act (PREA) for these applications because you have not yet submitted your pediatric assessment for the following:

PMR 1698-1: Deferred until September 30, 2023 [NDA 200534]
PMR 1695-1: Deferred until September 30, 2023 [NDA 200535]

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], 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.

While you are required to respond to this Non-Compliance letter as instructed above, you are not required to submit another deferral extension request, as we have received your February 5, 2024, deferral extension request, and it is currently under review.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-

under-505bd1-federal-food-drug-and-cosmetic-act 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 NDA with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, please contact Kimberly Compton, RPh, MS, RAC, Senior Regulatory Project Manager, at kimberly.compton@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

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/

RIGOBERTO A ROCA
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