



NDA 022402
NDA 202245

NOTIFICATION OF NON-COMPLIANCE WITH PREA

Hikma Pharmaceuticals USA Inc.
Attention: Tae Kim, PhD
Director, Clinical Development
1809 Wilson Road
Columbus, OH 43228

Dear Dr. Kim:

Please refer to your New Drug Applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Codeine Sulfate Tablet and Codeine Sulfate Oral Solution, which were approved on July 16, 2009, and June 30, 2011, respectively.

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 PMRs 26-10 and 1784-5, which were deferred until November 30, 2020. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

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. 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 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 NDAs with a cross-reference letter to the Investigational New Drug Application (IND) to which your protocol has been submitted.

If you have any questions, call LCDR Mavis Y. Darkwah, PharmD, GWCPM, RAC-US, Regulatory Project Manager, at (240) 402-3158.

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
12/22/2020 03:35:15 PM