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November 24, 2021

Rigoberto Roca, M.D., Director
Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP)
FDA/Center for Drug Evaluation and Research (CDER)
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: **NDA 021610: OPANA® ER (Oxymorphone Hydrochloride) Extended-Release Tablets**
Cross-Reference to IND 056919: Oxymorphhone Extended Release (ER) Tablets
RESPONSE TO PREA NONCOMPLIANCE LETTER; DEFERRAL EXTENSION REQUESTED

Dear Dr. Roca:

Reference is made to NDA 021610 for Opana ER® approved on June 22, 2006 and cross-reference is made to IND 056919. The purpose of this submission is to respond to FDA's October 12, 2021 Notification of Non-compliance with PREA Letter pertaining to PMR 289-2. Further reference is made to FDA's Jan. 31, 2011, Jun. 24, 2013, Feb. 6, 2020 and Jun. 25, 2020, letters granting deferral requests for extension of the final report submission due dates for PMR 289-2, the last of which extended the deadline to December 2020.

Final reference is made to the following:

- Endo's May 31, 2012, correspondence notifying FDA that Endo had ceased shipping all strengths of the OPANA ER formulation previously marketed under NDA 021610.

- The Feb. 28, 2013, Type B meeting during which the Agency agreed to the use of reformulated OPANA ER (previously marketed under NDA 201655) in research intended to satisfy PMR 289-2 because the original formulation was being no longer produced.

- The fact that, on August 28, 2017, at FDA's request, Endo discontinued distribution of reformulated OPANA ER (previously marketed under NDA 201655).

- Endo's April 9, 2019, request for a Type B meeting to discuss the status of research intended to satisfy PMR 289-2 and possible next steps.

- FDA's Apr. 18, 2019, denial of the meeting request, stating that "it would be more expeditious for [Endo] to submit a waiver and/or deferral extension request with supporting justification."

- Endo's Sept. 20, 2019, waiver request.

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- FDA's Feb. 6, 2020, denial of the waiver request, [redacted] (b) (4)
- [redacted] (b) (4)
- [redacted] (b) (4) on Oct. 12, 2021, FDA issued the aforementioned Notification of Non-Compliance with PREA.
- [redacted] (b) (4)

As a company dedicated to compliance with applicable laws, including those of FDA, Endo is committed to working with the agency to fulfill its obligations under PREA. We are currently evaluating possible options [redacted] (b) (4), including a possible request for a meeting or teleconference with the Agency to discuss proposed next steps. To allow for these and other additional efforts, Endo respectfully requests a deferral extension to December 2024 for PMR 289-2.

This submission contains trade secret and confidential commercial information. This information is exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. § 552(b)(4), and may not be disclosed without the prior written authorization of Endo. Such disclosure is prohibited by the U.S. Criminal Code, 18 U.S.C. § 1905, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and FDA regulations, 21 C.F.R. § 20.61(c). See also Food Mktg Inst. v. Argus Leader Media, No. 18-481 (U.S. Jun. 24, 2019). Redaction of this information is also required prior to posting of a response to a PREA non-compliance letter. See 21 U.S.C. § 355c(d)(1). Accordingly, Endo requests advance notice of FDA's proposed redactions and a meaningful opportunity to respond prior to posting.

If there are any questions concerning this submission, please do not hesitate to contact me at 845-364-4720 or via email at malandro.lisa@endo.com.

Sincerely,

Lisa Malandro

Lisa Malandro,
VP & Global Head Regulatory Affairs, Regulatory Affairs