



NDA 209819/S-012

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENTS
RELEASE OF POSTMARKETING COMMITMENT**

Indivior Inc.
10710 Midlothian Turnpike
Suite 125
North Chesterfield, VA 23235

Attention Rachel Capone
Manager, Regulatory Affairs

Dear Ms. Capone:

Please refer to your supplemental new drug application (sNDA) dated and received August 23, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SUBLOCADE (buprenorphine extended-release) injection for subcutaneous use.

This Prior Approval sNDA proposes to revise the DOSAGE AND ADMINISTRATION section (2.3 Recommended Dosing) of the package insert based on the final clinical study report for PMC 3308-8, submitted on May 31, 2018.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING COMMITMENTS

We have received your submission dated May 31, 2018, containing the final reports for the following postmarketing commitments listed in the November 30, 2017, approval letter.

- 3308-8 Conduct an analysis of previously collected pharmacokinetic (PK) data to compare the safety and efficacy of SUBLOCADE given monthly to SUBLOCADE given at a longer inter-dose interval. PK data have suggested that there is accumulation of SUBLOCADE over time, and that some patients may be adequately treated at a longer interval which may reduce patient burden and improve adherence.

- 3308-10 Conduct a pharmacokinetic (PK) analysis to evaluate the transition of patients with long term stability on a transmucosal buprenorphine dose to a monthly dose of SUBLOCADE without the use of a loading dose. Establish the cutoff dose for which patients may be converted to 100 mg monthly vs. 300 mg monthly.

We have reviewed your submission and conclude that the above commitments were fulfilled.

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

RELEASE OF POSTMARKETING COMMITMENT

Furthermore, the approval letter dated November 30, 2017, stated that you were to conduct the following post marketing commitment.

- 3308-9 If the analysis of pharmacokinetic data does not successfully address the safety and efficacy of SUBLOCADE given at a dosing interval longer than monthly, conduct a study to compare the safety and efficacy of SUBLOCADE given monthly to SUBLOCADE given at a longer inter-dose interval. The studied interval should be determined by PK modeling and prediction of the duration of clinically-effective plasma levels.

After reviewing your report for PMC 3308-8 we have determined that you are released from the PMC 3308-9, because it is no longer needed; the analyses submitted in the report for PMC 3308-8 successfully addressed the safety and efficacy of SUBLOCADE given at a dosing interval longer than monthly.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the November 30, 2017, approval letter that are still open.

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 Swati Patwardhan, Regulatory Project Manager, at 301-796-4085.

Sincerely,

{See appended electronic signature page}

Rigoberto A. Roca, MD
Director (Acting)
Division of Anesthesiology, Addiction Medicine
and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide

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
02/04/2020 07:08:19 AM