



NDA 020732/S-020  
NDA 020733/S-024  
NDA 022410/S-034

**SUPPLEMENT APPROVAL**

Indivior Inc.  
10710 Midlothian Turnpike  
Suite 430  
Richmond, VA 2323

Attention: Rachel Capone  
Manager, Regulatory Affairs

Dear Ms. Capone:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 28, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 020732/S-020, SUBUTEX (buprenorphine) sublingual tablet; NDA 020733/S-024, SUBOXONE (buprenorphine and naloxone) sublingual tablet; NDA 022410/S-034, and SUBOXONE (buprenorphine and naloxone) sublingual film.

These Prior Approval Supplemental New Drug Applications propose changes to the approved Medication Guide, aligning them to the changes in the package insert pertaining to risks of life-threatening respiratory depression and death with concomitant use of buprenorphine with benzodiazepines or other CNS depressants, and to improve patient understanding of the serious risks associated with SUBOXONE sublingual film, SUBOXONE sublingual tablet and SUBUTEX sublingual tablet, which were approved on February 1, 2018.

**APPROVAL & LABELING**

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

**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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes 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 titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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(l)(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).

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

NDA 020732/S-020  
NDA 020733/S-024  
NDA 022410/S-034  
Page 3

If you have any questions, call Swati Patwardhan, Regulatory Project Manager, at 301-796-4085.

Sincerely,

*{See appended electronic signature page}*

Rigoberto Roca, MD  
Deputy Director  
Division of Anesthesia, Analgesia,  
and Addiction products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURES:

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  
10/31/2019 09:10:50 PM