

NDA 207932/S-010

SUPPLEMENT APPROVAL

BioDelivery Sciences International, Inc.
4131 Park Lake Avenue
Suite 225
Raleigh, NC 27612

Attention: Drusilla Scott, PhD
Vice-President, Regulatory Affairs

Dear Dr. Scott:

Please refer to your supplemental new drug application (sNDA) dated and received November 9, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BELBUCA (buprenorphine buccal film).

This “Changes Being Effected in 30 days” supplemental new drug application provides for revisions to the package insert and package labeling to comply with our request letter dated September 28, 2018, which included following changes:

1. Revision of the established name to “Buprenorphine buccal film” on the container labeling to match the prescribing information (PI).
2. Revision of the DOSAGE FORMS AND STRENGTHS section of the PI to indicate the product contents in a manner that allows the reader to understand whether the strength is based on the active moiety or active ingredient (salt).
3. Including an equivalency statement to indicate the amount of active moiety related to the amount of active ingredient (salt) on the immediate container and carton labels as well as the PI.

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 agreed-upon labeling text approved October 7, 2019, with Supplement 012.

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 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(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).

CARTON AND CONTAINER LABELING

We acknowledge your February 7, 2019, submission containing final printed carton and container labeling.

REPORTING REQUIREMENTS

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

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

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>.

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

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling

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/

SHARON H HERTZ
10/16/2019 05:00:34 PM