



NDA 209184/S-001

**SUPPLEMENT APPROVAL**

Acorda Therapeutics, Inc.  
Attention: Todd Baumgartner, MD, MPH  
Senior Vice President, Regulatory Affairs  
420 Saw Mill River Road  
Ardsley, NY 10502

Dear Dr. Baumgartner:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 1, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INBRIJA (Levodopa Inhalation Powder) Capsules, 42 mg.

This “Changes Being Effected in 30 Days” supplemental new drug application provides to add two new secondary packaging configurations as below and associated labeling changes:

1. Carton containing 4 Inbrija capsules (1 blister card containing 4 capsules) and 1 Inbrija inhaler and Package Inserts.
2. Carton containing 12 Inbrija capsules (3 blister cards containing 4 capsules each) and 1 Inbrija inhaler and Package Inserts.

*Please note, by letters dated [September 6, 2016](#) and [August 9, 2018](#), we clarified for device constituents, other than devices that are implantable, life-sustaining or life-supporting, of 21 CFR 3.2(e)(3) (commonly referred to as “cross-labeled”) combination products assigned to Center for Drug Evaluation and Research (CDER) for premarket review and regulation, the compliance date for UDI label (21 CFR 801.20) requirements is September 24, 2018, and GUDID submission (21 CFR 830.300) requirements is September 24, 2019. In your response dated August 16, 2019, you cite enforcement discretion policy under FDA’s “Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marketing – Immediately in Effect Guidance for Industry and Food and Drug Administration Staff (issued November 5, 2018)”. Please note this policy does not apply to device constituents of combination products.*

*The FDA requires device labelers to comply with UDI requirements according to the dates established in conjunction with the UDI Rule. We believe the implementation schedule outlined in the final UDI Rule has given labelers adequate time to comply with all applicable UDI labeling and data submission requirements by this time. We expect all labelers to be making diligent efforts to fulfill their UDI obligations. Labelers with questions about complying with UDI labeling and data submission requirements may*

access additional information at <https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/prepare-gudid> or contact the [FDA UDI Help Desk](#).

## **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.

## **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, text for the patient information, and instructions for use) 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 via 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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 IMMEDIATE CONTAINER LABELS**

Submit final printed carton labels that are identical to enclosed carton labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 209184/S-001.**” Approval of this submission by FDA is not required before the labeling is used.

**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 Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

*{See appended electronic signature page}*

David Lewis, Ph.D.  
Branch Chief, Branch II  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling

Carton and Container Labeling



David  
Lewis

Digitally signed by David Lewis

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