

NDA 209184/S-005 and S-007

## SUPPLEMENT APPROVAL

Acorda Therapeutics, Inc.  
Attention: Todd F. 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 applications (sNDAs) dated March 5, 2020 and May 20, 2020, received March 5, 2020 and May 20, 2020, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Inbrija (Levodopa Inhalation Powder) 42 mg.

These Prior Approval supplemental new drug applications provide for the following:

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|-------|---|
| S-005 | To add a section 6.2 Postmarketing Experience for cough/choking sensation.          |
| S-007 | To add a step in the IFU to address complaints of “no whirl” and “device clogging”. |

### **APPROVAL & LABELING**

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

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*.<sup>2</sup>

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).

If you have any questions, please contact Stacy Metz, PharmD, Senior Regulatory Project Manager, at [stacy.metz@fda.hhs.gov](mailto:stacy.metz@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Eric Bastings, MD  
Director (acting)  
Division of Neurology 1  
Office of Neuroscience  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use

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<sup>2</sup> 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>.

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**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.**  
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/s/  
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