DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205474/S-003

**SUPPLEMENT APPROVAL**

Sovereign Pharmaceuticals, LLC
7590 Sand Street
Fort Worth, TX 76118

Attention: Leonard Lawrence, BS, MBA, RAC
Manager Regulatory Affairs

Dear Mr. Lawrence:

Please refer to your Supplemental New Drug Application (sNDA) dated October 10, 2016 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Obredon (hydrocodone bitartrate and guaifenesin) Oral Solution.

We also refer to our letter dated August 31, 3016, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Obredon Oral Solution. This information pertains to the serious risks of profound sedation, respiratory depression, coma, and death associated with the concomitant use of opioids and benzodiazepines or other central nervous system depressants, including alcohol.

This supplemental new drug application provides for revisions to the labeling for Obredon Oral Solution, consistent with our August 31, 2016 correspondence.

## 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 and with the revisions listed below and included in the enclosed labeling.

1. In the Recent Major Changes of the Highlights, the section headings and if appropriate, subsection heading of the labeling section affected by the change must be listed together with each section's identifying number and the date and on which the change was incorporated in labeling. In the Recent Major Changes of the Highlights, the section title Warnings and Precautions was added.

2. The same title for the Boxed Warning that appears in the Highlights and Table of Contents must also appear in the Full Prescribing Information, the Box Warning was added to the Full Prescribing Information.

These revisions were added to comply with the Physician Labeling Rule.

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**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 package insert and text for the 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 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).

**IMMEDIATE CONTAINER LABEL**

Submit the final printed immediate container label that is identical to the enclosed immediate container label, as soon as it is available, but no more than 30 days after it is printed. Please submit this label electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* For administrative purposes, designate this submission "**Final Printed Container Label for approved NDA 205474/S-003**." Approval of this submission by FDA is not required before the labeling is used.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

**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 Carol F. Hill, Senior Regulatory Senior Project Manager, at (301) 796-1226.

Sincerely,

*{See appended electronic signature page}*

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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SALLY M SEYMOUR
01/13/2017