



NDA 205474

NDA APPROVAL

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

Dear Mr. Lawrence:

Please refer to your New Drug Application (NDA) dated January 13, 2014, received January 14, 2014 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for hydrocodone and guaifenesin oral solution, 2.5 mg, 200 mg/5mL.

We acknowledge receipt of your amendments dated January 15, February 28, March 11 and 18, April 4, 10, and 30, May 19 and 30, June 6, 12 and 23, July 1, 18, 22, August 11, November 6, 10, and 13, 2014.

This new drug application provides for the use of Obredon, (hydrocodone/guaifenesin) oral solution for symptomatic relief of cough and to loosen mucous associated with the common cold. We have completed our review of this application. 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 package insert. 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container 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 (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **“Final Printed Carton and Container Labels for approved NDA 205474.”** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

We are waiving the pediatric study requirement for ages zero to less than 6 years, because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric group. The use of hydrocodone in children under the age of 6 years has been associated with fatal respiratory depression.

We are deferring submission of your pediatric studies for ages 6 to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. These required studies are listed below.

- 2826-1 Conduct a study to assess the pharmacokinetics of each drug component of hydrocodone and guaifenesin in children ages 6 to 17 years with symptoms of the common cold.

Final Protocol Submission: 03/2015
Study Completion: 09/2016
Final Report Submission: 03/2017

- 2826-2 Conduct a study to assess the safety of hydrocodone and guaifenesin in children ages 6 to 17 years with symptoms of the common cold. The dose used in this study will be based upon the results of the pharmacokinetic study in children ages 6 to 17 years (PMR 2826-1).

Final Protocol Submission: 09/2018
Study Completion: 03/2022

Final Report Submission: 09/2022

Submit the protocols to your IND 106992, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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, contact Laura Musse, Regulatory Health Project Manager, at
(240) 402-3720

Sincerely,

{See appended electronic signature page}

Lydia Gilbert-McClain, M.D.
Deputy Director
Division of Pulmonary, Allergy, and Rheumatology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling

Carton and Container Labeling

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

/s/

LAURA MUSSE

11/14/2014

LYDIA I GILBERT MCCLAIN

11/14/2014