SOVEREIGN
PHARMACEUTICALS, LLC

April 28, 2017
IND No. (b) (4)
Serial Number 0021
DEFERRAL EXTENSION REQUEST-PMR 2826-1

RECONSIDERATION OF THE APPROPRIATENESS OF
THE CONTRAINDICATED NARCOTICS DOSING TO
CHILDREN AND ADOLESCENTS UNDER THE AGE OF 18

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and
Rheumatology Products, ODE II
Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Request for a Deferral Extension Request-PMR 2826-1 for Obredon® Oral Solution (Hydrocodone Bitartrate and Guaifenesin Oral Solution), 2.5 mg; 200 mg/5 mL

To Dr. Seymour:

Sovereign Pharmaceuticals, LLC (Sovereign) makes reference to its filing to the FDA via the ESG on March 31, 2017 regarding a request for a 4 week extension for submitting the deferral extension request PMR 2826-1. Sovereign also makes reference to a FDA Letter dated April 11, 2017 entitled "Notice of Non-Compliance with PREA". Sovereign formally requested that a 4 week extension be provided in order to respond to the FDA regarding the missed PK Study Final Report date of March 2017. This letter represents Sovereign's deferral extension request.

Sovereign formally requests reconsideration, justification, and appropriateness evaluation of the PSP (Pediatric Study Plan) established at the time of approval of NDA 205474 for Obredon® Oral Solution (Hydrocodone Bitartrate and Guaifenesin Oral Solution 2.5 mg; 200 mg/5mL). New data and information have been made available to FDA, which FDA has made public that requires reconsideration and possibly a revocation of the 2014 PSP and the agency's call for clinical studies in children.

Specifically, it is now known that the use of codeine-containing cough-and-cold medicines like Obredon is dangerous for children and contraindicated in the pediatric population. There is a real concern, therefore, that the conduct of pediatric clinical studies could be unethical and contrary to human subject protections. Moreover, Sovereign is concerned that it would be unable to obtain approval from an Investigational Review Board (IRB) to conduct a study in children that dosed them with Obredon. Sovereign supports its request with the following information.

2 Pages have been Withheld in Full as b4 (CCI/TS) immediately following this page

SOVEREIGN
PHARMACEUTICALS, LLC

The files in this submission have been scanned with Bitdefender Endpoint Security Tools, Version 6.2.19.899 and no viruses have been detected. The estimated size of this application is 7 MB.

If you have any comments or questions please feel free to contact Leonard Lawrence at the contact information listed below.

Sincerely,

Leonard Lawrence

Leonard Lawrence, BS, MBA, RAC
Manager, Regulatory Affairs
Sovereign Pharmaceuticals, LLC
7590 Sand Street
Fort Worth, TX 76118
Phone: 817-284-0429, ext. 152
Fax: 817-284-0531
e-mail: llawrence@sovpharm.com

cc: John Jenkins, Director, FDA CDER Office of New Drugs
Carol Hill, Regulatory Health Project Manager, FDA CDER DPARP
Congressman Dr. Burgess C/O Melanie Torez