insys
THERAPEUTICS, INC.

February 17, 2017

Joyce Korvick, MD, MPH
Deputy Director for Safety, Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland, 20993

Re: NDA 205525: SYNDROS™ (Dronabinol) Oral Solution
RESPONSE TO PREA NON-COMPLIANCE
DEFERRAL EXTENSION REQUESTED

Dear Dr. Korvick,

Reference is made to NDA #205525 for SYNDROS (Dronabinol) Oral Solution. Pursuant to your letter dated 2/07/2017, which informed Insys that we did not meet the postmarketing requirement of the Pediatric Research Equity Act for failure to submit a pediatric assessment by January 31, 2017, and to our discussion with the Division, we are resubmitting this request to include the reasoning for missing the deadline. As provided to the Division, Insys is currently preparing the report identified as 3044-1. Unfortunately, the report may not be complete until March. Thus, Insys is requesting a deferral extension until March 31, 2017.

The reason why Insys was not able to comply with the deadline for submitting the final report for 3044-1 was due to the Contract Research Organization's (CRO) failure to perform the toxicokinetic analysis (TK) at the requested time. Although the samples were delivered in time, the analysis did not begin when requested in an E-mail from Insys dated December 7, 2016. A follow up E-mail was sent on January 11, 2107, to inquire on the progress of the study. In response to these E-mails, the CRO stated on January 13, 2017, that due to a "communication error on our end we had missed one of the process steps that initiates our PK group to begin," resulting in a delay of approximately one month, delaying our submission according to the timelines established in our post-marketing requirements. After several back and forth E-mail exchanges, the draft toxicokinetic report was provided to the original CRO that conducted the study to incorporate these toxicokinetic results into the final study report. In speaking with the original CRO that is writing the final report, it should be available by the end of March at the latest.

To mitigate any future occurrences of this happening in the future, Insys will track the progress of its CROs much more carefully.

INSYS THERAPEUTICS, INC.

Should any questions arise, please do not hesitate to contact me. I can be reached via telephone at 480-500-3150, by fax at 602-910-2627, or by e-mail at ssherman@insysrx.com.

Sincerely,

Stephen W Sherman

Stephen Sherman
Sr. Vice President, Regulatory Affairs

CC: Maureen Dewey, MPH, Senior Regulatory Project Manager

Electronic Submission Specifications

This submission is compliant with FDA's Guidelines for Industry and current eCTD specifications.

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

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