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August 18, 2016

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: DMF #: 027320
Holder: McKesson Specialty Health (McKesson)
DMF Subject: Transmucosal Immediate Release Fentanyl (TIRF) Access Program
Re: REMS Shared Program
DMF Type: V
DMF Submission Information: DMF Annual Report
REMS Submission Identifier: Not Applicable
eCTD Sequence Number: 0024

Dear Drug Master File Staff:

This Type V DMF contains the Risk Evaluation and Mitigation Strategy (REMS) for Transmucosal Immediate Release Fentanyl for the Shared System REMS program.

Reference is made to the above DMF, which was initially submitted on August 20, 2013. Enclosed, please find the DMF Annual Report (Reporting Period: August 21, 2015 – August 20, 2016). The Annual Report includes an administrative information page, a summary of the amendments that have been submitted during this reporting period, and a list of authorized persons to incorporate by reference.

McKesson states that information provided in this Master File is current and assures that the material furnished will meet the specifications described herein. McKesson also confirms that the Holder obligations are observed.

We request that all information in this file be treated as confidential commercial information by the Food and Drug Administration pursuant to 21 C.F.R. §20.61, and that no information from this file be provided to any unauthorized persons without the express written consent of the DMF holder.

If you have any questions or concerns, please do not hesitate to contact Gina Melazzo, U.S. Agent for McKesson, at 610-407-1732 or alternatively via email at gina.melazzo@accenture.com.

Sincerely,

Diane Tuska for

Gina Melazzo, Senior Regulatory Affairs Project Manager
U.S. Agent Accenture, LLP

Attachments: Table of Contents for the submission
Electronic Submission Specifications

ANNUAL REPORT
Reporting Period: August 21, 2015 – August 20, 2016

Module Section	**Description**
1.2 Cover Letter	Cover Letter w/ Attachments
1.11.3 – Efficacy Information Amendment	Annual Report - Summary of Changes
1.4.3 – List of Authorized Persons to Incorporate by Reference	List of Authorized Persons

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.

Anti-Virus Program	Symantec Endpoint Protection Edition
Program Version	12.1.5337.5000
Virus Definition Date	08/03/2016 rev. 1
Submission Size	Approx. 405 KB

The IT point of contact for this submission is:

Name	Matt Francis
Phone Number	1-610-407-1854
Email Address	Matthew.p.francis@accenture.com

ADMINISTRATIVE INFORMATION

Holder's Name: McKesson Specialty Health (McKesson)

Holder's Address: 4343 N. Scottsdale Road
Suite 150
Scottsdale, AZ 85251

Holder's Contact Person: Laura Baloun

Contact's Address: 4343 N. Scottsdale Road
Suite 150
Scottsdale, AZ 85251

Contact's Phone: 480-663-4009

Contact's Fax: 480-663-4973

Contact's Email address: laura.baloun@mckesson.com

Statement of Commitment: Attached, please find a signed statement of commitment. The statement certifies that the DMF is current and that McKesson will comply with the statements made in it.

Agent's Name: Accenture, LLP

Agent's Address: 1160 West Swedesford Road
Berwyn, PA 19312

Agent's Contact Person: Gina Melazzo

Contact's Address 1160 West Swedesford Road
Berwyn, PA 19312

Contact's Phone: 610-407-1732

Contact's Fax: 610-407-8433

Contact's E-mail address: gina.melazzo@accenture.com

3. List of Authorized Persons to Incorporate by Reference

(Annual Report - Reporting Period: August 21, 2015 – August 20, 2016)

The following is a complete list of persons authorized to incorporate information in the DMF by reference:

- Actavis Laboratories Inc. – June 17, 2015
- BioDelivery Sciences International, Inc. – March 20, 2015
- Cephalon, Inc. – August 28, 2013
- Depomed, Inc. – August 28, 2013
- Insys Therapeutics, Inc. – August 28, 2013
- Mallinckrodt – August 28, 2013
- Mylan – August 28, 2013
- Par Pharmaceutical, Inc. – August 28, 2013
- Sentynl Therapeutics Inc. – January 15, 2016

Please note that during the reporting period, McKesson submitted a letter of authorization for Sentynl Therapeutics Inc. and withdrew authorization for Galena BioPharma, Inc.

ANNUAL REPORT - SUMMARY OF CHANGES

Reporting Period: August 21, 2015 – August 20, 2016

Date / Sequence	Description
October 12, 2015 / 0018	Response to FDA Information Request – 36-Month Assessment Report
December 28, 2015 / 0019	Assessment 5 at 4 Years
January 15, 2016 / 0020	Letter of Authorization for Sentynl Therapeutics, Inc.
January 15, 2016 / 0021	Letter of Withdrawal for Galena BioPharma, Inc.
April 15, 2016 / 0022	Change in Agent
May 4, 2016 / 0023	48-Month Supplemental Assessment Report

For further details regarding the above REMS amendments, please see the REMS History (Sequence 0023).