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August 20, 2014

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: 0011

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, 2013 – August 20, 2014). The Annual Report includes an administrative information page, a summary of the amendments that have been submitted since the original DMF, 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 to 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 written consent.

If you have any questions or concerns, please do not hesitate to contact Jann Kochel, U.S. Agent for McKesson, at 610-407-1738 or alternatively via email at jann.a.kochel@accenture.com.

Sincerely,

for Jann A. Kochel

Jann A. Kochel, U.S. Agent
Accenture, LLP

Attachments: Table of Contents for the submission
Electronic Submission Specifications

ANNUAL REPORT
Reporting Period: August 21, 2013 – August 20, 2014

Electronic Submission Specifications

This submission is compliant with FDA's Guideline for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway. This eCTD has been generated by Accenture, LLP (formerly Octagon Research Solutions Inc.), who has filed an acceptable eCTD pilot with the Center (Pilot Number 900777).

Anti-Virus Program	Symantec Endpoint Protection Edition
Program Version	11.0.5002.333
Virus Definition Date	08/11/2014 rev. 3
Submission Size	Approx. 1 MB

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

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: Jann A. Kochel

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

Contact's Phone: 610-407-1738

Contact's Fax: 610-407-8433

Contact's E-mail address: jann.a.kochel@accenture.com

3. List of Authorized Persons to Incorporate by Reference

(Annual Report - Reporting Period: August 21, 2013 – August 20, 2014)

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

- Cephalon, Inc. – August 28, 2013
- Depomed, Inc. – August 28, 2013
- Galena BioPharma, Inc. – August 28, 2013
- Insys Therapeutics, Inc. – August 28, 2013
- Mallinckrodt – August 28, 2013
- Meda Pharmaceuticals, Inc. – August 28, 2013
- Mylan – August 28, 2013
- Par Pharmaceutical, Inc. – August 28, 2013

Please note that the list is unchanged since the original submission.

ANNUAL REPORT - SUMMARY OF CHANGES

Reporting Period: August 21, 2013 – August 20, 2014

Date / Sequence	Description
September 04, 2013 / 0001	Response to Administrative Filing Issue
September 09, 2013 / 0002	REMS Modification 1
September 12, 2013 / 0003	Assessment 1 at 6 Months
September 16, 2013 / 0004	REMS Modification 2 - Draft
September 18, 2013 / 0005	Assessment 2 at 12 Months
September 23, 2013 / 0006	REMS Modification 2 – Final
December 27, 2013 / 0007	Assessment 3 at 24 Months
March 31, 2014 / 0008	Assessment Methodology – RADARS System Report
May 20, 2014 / 0009	REMS Modification 3 – Draft
May 30, 2014 / 0010	Response to FDA Request for Information, dated May 16, 2014

For further details regarding the above amendments, please see the REMS History (Sequence 0010).