



Accenture LLP  
1160 West Swedesford Road  
Berwyn, PA 19312  
www.accenture.com

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: Clinical/Clinical Information**  
**REMS Submission Identifier: Assessment Methodology - Other**  
**eCTD Sequence Number: 0008**

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.

Included in this submission, please find the RADARS System Report – Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS): Surveillance Monitoring covering the period of July 1, 2012 through September 30, 2013.

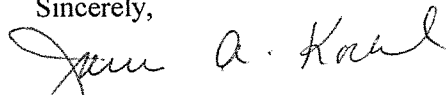
We also wish to inform the Agency that Accenture LLP, U.S. Agent, has relocated offices. The Administrative Information Page has been updated to reflect the new address and phone numbers.

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](mailto:jann.a.kochel@accenture.com).

Sincerely,

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

Attachments: Table of Contents for the submission  
Electronic Submission Specifications

Assessment Methodology - Other

Module Section	Description
1.2 Cover Letter	Cover Letter w/ Attachments Administrative Information Page
1.16 – Risk Management Plans	REMS History RADARS System Report – Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS): Surveillance Monitoring covering the period of July 1, 2012 through September 30, 2013

## 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).

<b>Anti-Virus Program</b>	Symantec Endpoint Protection Edition
<b>Program Version</b>	11.0.5002.333
<b>Virus Definition Date</b>	04/25/2014 rev. 9
<b>Submission Size</b>	Approx. 2 MB

The IT point of contact for this submission is:

<b>Name</b>	Matt Francis
<b>Phone Number</b>	1-610-407-1854
<b>Email Address</b>	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

Modification No.	Date Approved	Documents Affected	Overview of Modification
1	June 5, 2012	<ul style="list-style-type: none"> <li>• REMS</li> <li>• Prescriber Program Overview</li> <li>• Education Program</li> <li>• Prescriber Enrollment Form</li> <li>• Patient Provider Agreement Form</li> <li>• Patient and Caregiver Overview</li> <li>• Dear Healthcare Provider Letter</li> <li>• Outpatient Pharmacy Overview</li> <li>• Chain Pharmacy Overview</li> <li>• Inpatient Pharmacy Overview</li> <li>• Outpatient Pharmacy Enrollment Form</li> <li>• Chain Pharmacy Enrollment Form</li> <li>• Inpatient Pharmacy Enrollment form</li> <li>• Outpatient Pharmacy Letter</li> <li>• Inpatient Pharmacy Letter</li> <li>• Dear Distributor Letter</li> <li>• Distributor Enrollment Form</li> <li>• Supporting Document</li> </ul>	<p><b>Sequence 0002:</b>            Edits to Patient-Prescriber Agreement Form, the addition of the Closed System Pharmacy Enrollment Form*, the addition of the newly approved TIRF product, Subsys (fentanyl sublingual spray) and minor editorial changes.</p> <p>*The Closed System Pharmacy Enrollment Form was not formally submitted through the Gateway but was submitted via email on May 18, 2012 and included in the June 5, 2012 FDA approval letter.</p>
N/A	N/A	Assessment Report 1 at 6 months – due 06/28/2012	<b>Sequence 0003:</b> Assessment report covering 12/28/2011 to 04/27/2012
2	November 7,	Draft Documents	<b>Sequence 0004:</b>

	2013	submitted on or before 09/28/2012 <ul style="list-style-type: none"> <li>• Chain Pharmacy Enrollment Form</li> <li>• Outpatient Pharmacy Enrollment Form</li> <li>• Closed System Pharmacy Overview</li> <li>• Education Program</li> <li>• Frequently Asked Questions (FAQ)</li> <li>• Outpatient Pharmacy Letter</li> <li>• REMS</li> <li>• Supporting Document</li> </ul>	Modification proposed to: <ul style="list-style-type: none"> <li>• Incorporate closed system pharmacies into the TIRF REMS Access Program</li> <li>• Correct minor inconsistencies between the FDA provided versions and the current PDF versions of REMS materials</li> </ul>
N/A	N/A	Assessment Report 2 at 1 year – due 12/28/2012	<b>Sequence 0005:</b> Assessment report covering 04/28/2012 to 10/28/2012
2	November 7, 2013	Amendment to 09/28/2012 supplement: <ul style="list-style-type: none"> <li>• Chain Outpatient Pharmacy Enrollment Form</li> <li>• Independent Outpatient Pharmacy Enrollment Form</li> <li>• Closed System Outpatient Pharmacy Enrollment Form</li> <li>• Inpatient Pharmacy Enrollment Form</li> <li>• Distributor Enrollment Form</li> <li>• Prescriber Enrollment Form</li> <li>• Patient Provider Agreement Form</li> <li>• Chain Outpatient</li> </ul>	<b>Sequence 0006:</b> Modification proposed to: <ul style="list-style-type: none"> <li>• Revised terminology, processes, and definitions for outpatient pharmacies</li> <li>• Revised attestations for physicians and patients to address concerns regarding patient access</li> <li>• Revised Program Overview and Frequently Asked Questions to improve clarity and content</li> <li>• Updated REMS materials to reflect the completion of the transition phase for the TIRF REMS Access Program</li> </ul>

		Pharmacy Overview <ul style="list-style-type: none"> <li>• Independent Outpatient Pharmacy Overview</li> <li>• Closed System Outpatient Pharmacy Overview</li> <li>• Inpatient Pharmacy Overview</li> <li>• Patient and Caregiver Overview</li> <li>• Prescriber Overview</li> <li>• Education Program</li> <li>• Knowledge Assessment</li> <li>• Frequently Asked Questions (FAQ)</li> <li>• Dear Outpatient Pharmacy Letter</li> <li>• Dear Inpatient Pharmacy Letter</li> <li>• Dear Healthcare Provide Letter</li> <li>• Dear Distributor Letter</li> <li>• REMS</li> <li>• Supporting Document</li> <li>• Website Landing Page</li> </ul>	
N/A	N/A	Assessment Report 3 at 2 years – due 12/28/2013	<b>Sequence 0007:</b> <b>Assessment report covering 10/29/2012 to 10/28/2013</b>
N/A	N/A	Safety Surveillance Report #1 – due 03/31/2014	<b>Sequence 0008:</b> <b>Safety surveillance data covering Q4 2012 to Q3 2013</b>



**RADARS<sup>®</sup> System Report**

**Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS): Surveillance Monitoring**

**For**

**Cephalon, Inc. (a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.)**

**Depomed, Inc.**

**Galena Biopharma, Inc.**

**Insys Therapeutics Inc.**

**Mallinckrodt Pharmaceuticals**

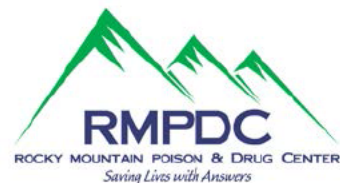
**Meda Pharmaceuticals, Inc.**

**Mylan, Inc.**

**Par Pharmaceutical, Inc.**

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FOLLOWING THIS PAGE, FDA\_7600 TO FDA\_7680 WITHHELD IN FULL AS B(4)/CCI

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**FDA\_7599**