



FILE COPY

**Confidential -- Not For Public Disclosure**

March 5, 2010

**VIA OVERNIGHT MAIL DELIVERY**

Thomas Abrams, RPh, MBA  
Director  
Division of Drug Marketing, Advertising, and Communications  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**RE: NDA 20-616  
Kadian® (morphine sulfate extended-release) Capsules, CII  
MACMIS #18148**

Dear Mr. Abrams,

Reference is made to Actavis' March 4, 2010 response to the Warning Letter dated February 18, 2010 from the Division of Drug Marketing Advertising, and Communications, which concerns two promotional materials disseminated by Actavis. Upon subsequent review of that response, Actavis noted an error in the list of materials provided in Attachment C. Specifically, Attachment C erroneously lists the date of submission for the Co-Pay Assistance Program (KAD200901) as 2/16/10. The correct date of that submission is 2/16/09. Attached is revised Attachment C that accurately reports the date of submission. I apologize for any inconvenience that this error caused.

Please do not hesitate to contact me at 908-659-2317 if you have questions.

Sincerely,

Terri Nataline  
Vice President, Regulatory and Medical Affairs  
Actavis US

Enclosures

Actavis, Inc.

60 Columbia Rd., Bldg. B  
Morristown, NJ 07960

t (973) 993-4501

www.actavis.com



NDA 20-616  
Kadian® (morphine sulfate extended-release) Capsules, CII  
MACMIS #18148

cc: Elaine Hu Cunningham, Pharm. D., Senior Regulatory Review Officer  
CDER, DDMAC Communications  
(via facsimile: 301-847-8444)

Doug Boothe  
Chief Executive Officer  
Actavis US

**ATTACHMENT C**

**Kadian Materials for Which Actavis Ceased Further Distribution and Use**

<b>2253 Submission Date</b>	<b>Piece</b>	<b>Number Printed</b>	<b>Dates of Distribution</b>	<b>Method of Distribution</b>
02/16/09	Co-Pay Assistance Program (KAD200901)	177,000	March 2009-February 2010	Physician visits by sales team, website registration, telephone registration
06/24/09	Kadian "Behind the Scenes..." (KAD180229C)	15,000	June 2009 – February 2010	Physician visits by sales team
08/03/09	Kadian "When You Can Prescribe Benefits..." (KAD18D0231)	15,000	August 2009 – February 2010	Physician visits by sales team
10/20/09	Kadian Conversion Guide Sales Aid (KAD17D0179)	3,000	October 2009 – February 2010	Physician visits by sales team
10/29/09	Kadian Sales Aid (KAD18D0228)	1,000	October 2009 – February 2010	Physician visits by sales team
11/06/09	Kadian Reprint (KAD19ETOH)	2,000	November 2009 – February 2010	Physician visits by sales team

\*\*\*\*\* -COMM. JOURNAL- \*\*\*\*\* DATE MAR-05-2010 \*\*\*\*\* TIME 09:44 \*\*\*\*\*

MODE = MEMORY TRANSMISSION

START=MAR-05 09:43

END=MAR-05 09:44

FILE NO.=590

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-ACTAVIS

\*\*\*\*\* -REGULATORY AFF - \*\*\*\*\* 908 659 2250- \*\*\*\*\*



*Fax message*

To	Elaine Hu Cunningham, Pharm.D., Senior Regulatory Review Officer		
Date	03/05/10	Fax No	301-847-8444
No of pages (including this one)	4		
Subject	NDA 20-616 / MACMIS #18148		
From	Terri Nataline, Vice President, Regulatory and Medical Affairs		

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

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*Fax message*

To	Elaine Hu Cunningham, Pharm.D., Senior Regulatory Review Officer		
Date	03/05/10	Fax No	301-847-8444
No of pages (including this one)	4		
Subject	NDA 20-616 / MACMIS #18148		
From	Terri Nataline, Vice President, Regulatory and Medical Affairs		

<p>CARLA HEDRICK 908-659-2527 ACTAVIS ELIZABETH LLC 200 ELMORA AVENUE ELIZABETH NJ 072021106</p> <p><b>SHIP TO:</b> THOMAS ABRAMS, RPH, MBA, DIRECTOR FDA, CDER, DDMAC 5901-B AMMENDALE ROAD BELTSVILLE MD 20705-1266</p>	<p>0.0 LBS LTR 1 OF 1</p>	<p><b>MD 207 9-59</b></p> 	<p><b>UPS NEXT DAY AIR</b></p> <p><b>1</b></p> <p>TRACKING #: 1Z 062 077 01 9742 7345</p> 	<p>BILLING: P/P</p> <p>Reference#1: 20-616</p> <p>US 12.0.ZZ. WXP2E60 99.0A 01/2010</p>  <p>TM</p>
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## Proof of Delivery

Dear Customer,

This notice serves as proof of delivery for the shipment listed below.

**Tracking Number:** 1Z0620770197427345  
**Reference Number(s):** 20-616  
**Service:** NEXT DAY AIR  
**Shipped/Billed On:** 03/05/2010  
**Delivered On:** 03/08/2010 8:43 A.M.  
**Delivered To:** 5901B AMMENDALE RD  
BELTSVILLE, MD, US 20705  
**Signed By:** MANG

**Location:** RECEIVER

Thank you for giving us this opportunity to serve you.

Sincerely,

UPS

Tracking results provided by UPS: 03/08/2010 11:12 A.M. ET

<https://wwwapps.ups.com/WebTracking/processPOD?lineData=LAUREL%5EKB%5EUS%5E201003...> 3/8/2010