



FILE COPY

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November 1, 2010

**VIA OVERNIGHT MAIL DELIVERY
CONFIRMATION VIA FACSIMILE**

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 the Division of Drug Marketing, Advertising, and Communication's (DDMAC) August 4, 2010 letter in response to Actavis Elizabeth LLC's (Actavis) July 16, 2010 submission of its finalized dissemination plan and revised Dear Healthcare Professional (DHP) and Dear Consumer letters. Further reference is made to the February 18, 2010 DDMAC Warning Letter for Kadian[®] (morphine extended-release) Capsules, CII (Kadian).

This letter is to confirm that Actavis has completed disseminating the DHP and Dear Consumer letters in accordance with its commitments. The table below summarizes these dissemination activities:

Activity	Start Date	Completion Date
Sales Force Trained on Corrective Message	August 19, 2010	August 19, 2010
Delivery of Dear Consumer Letters and Stand to 10,456 Physician and Pharmacy locations	August 30, 2010	October 22, 2010
DHP Letter Mailing to 7,163 Healthcare Professionals	September 15, 2010	September 15, 2010
Dear Consumer Letter Mailing to 2,964 Consumers	September 24, 2010	September 27, 2010

Actavis Elizabeth LLC
Actavis Inc.

200 Elmora Avenue
Elizabeth, NJ 07207

☎ 908 527 9100
☎ 908 659 2250

www.actavis.com

AL-SF-01140

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NDA 20-616

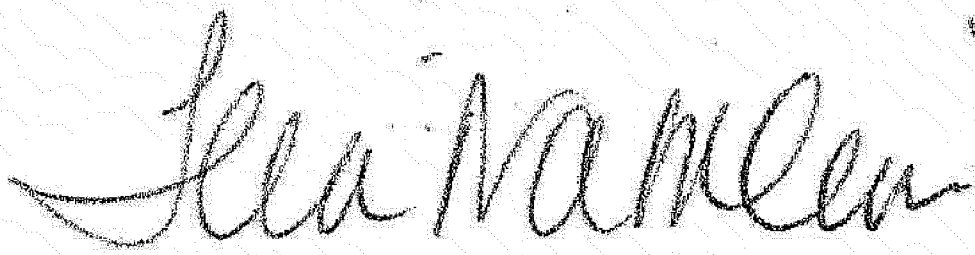
Kadian® (morphine sulfate extended-release) Capsules, CII
MACMIS #18148

Actavis representatives will now be conducting 30-day follow-up calls to each physician's office and pharmacy that received the Dear Consumer Letter package to ensure that there are a sufficient number of letters to fill the stands during the 90-day corrective action period.

A full report of the dissemination and follow-up activities will be provided to DDMAC at the conclusion of the 90-day corrective action period.

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

Sincerely,



Terri Nataline
Vice President, Regulatory and Medical Affairs
Actavis US

Enclosures

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

John LaRocca
Chief Legal Officer
Actavis US

***** -COMM. JOURNAL- ***** DATE OCT-31-2010 ***** TIME 23:37 *****

MODE = MEMORY TRANSMISSION

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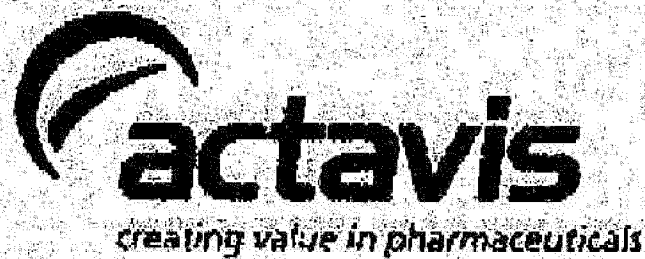
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-ACTAVIS

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



Fax message

To	Elaine Hu Cunningham, Pharm.D., Senior Regulatory Review Officer CDER, DDMAC Communications		
Date	11/01/10	Fax No	301-847-8444
No of pages (including this one)		3	
Subject	NDA 20-616 / MACMIS #18148		
From	Terri Nataline, Vice President, Regulatory and Medical Affairs		

Hard copy to follow via UPS Overnight Courier.



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To	Elaine Hu Cunningham, Pharm.D., Senior Regulatory Review Officer CDER, DDMAC Communications		
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Subject	NDA 20-616 / MACMIS #18148		
From	Terri Nataline, Vice President, Regulatory and Medical Affairs		

Hard copy to follow via UPS Overnight Courier.

CARLA HEDRICK 908-659-2527 ACTAVIS ELIZABETH LLC 200 ELMORA AVENUE ELIZABETH NJ 072021106		0.0 LBS LTR	1 OF.1
SHIP TO: THOMAS ABRAMS, RPH., MBA FDA, CDER, DDMAC 5901-B AMMENDALE ROAD BELTSVILLE MD 20705-1266			
		MD 207 9-59 	
UPS NEXT DAY AIR		1	
TRACKING #: 1Z 062 077 01 9112 8125			
			
BILLING: P/P			
UTS 12.8.10.		WXPRES0 09.0A 10/2010	
			

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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

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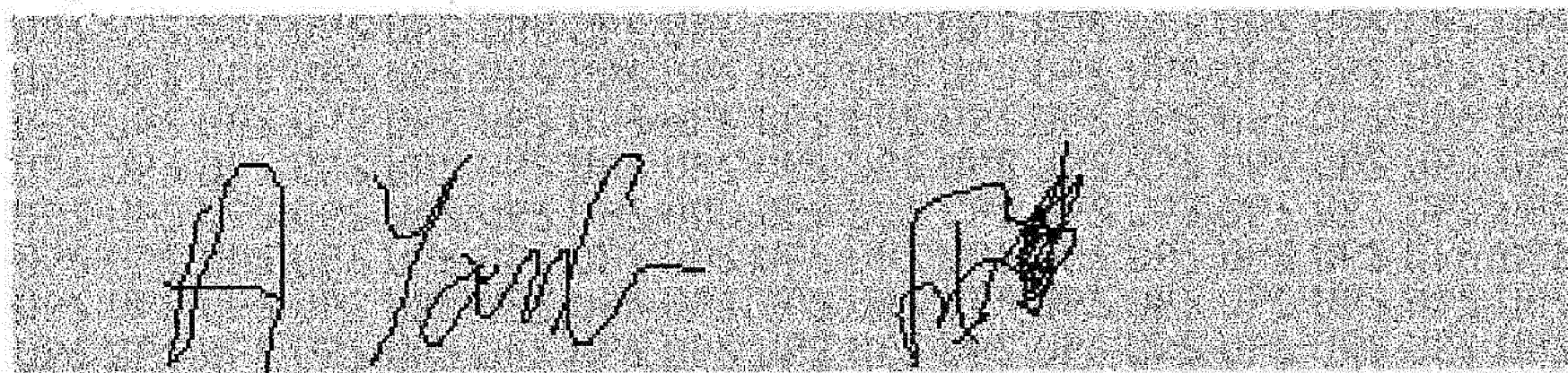
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**Proof of Delivery**

Dear Customer,

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

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Service: NEXT DAY AIR
Shipped/Billed On: 11/01/2010
Delivered On: 11/02/2010 9:41 A.M.
Delivered To: 5901 AMMENDALE RD
BELTSVILLE, MD, US 20705
Signed By: YOUNG

**Location:** RECEIVER

Thank you for giving us this opportunity to serve you.

Sincerely,

UPS

Tracking results provided by UPS: 11/03/2010 3:35 P.M. ET