

**From:** Cristina Garcia  
**Sent:** Thursday, September 15, 2011 8:52 AM  
**To:** Jennifer Altier  
**Cc:** Joann Stavole; Charlene Salmorin  
**Subject:** Released - KADI1124 & KADI1128  
**Attachments:** KADI1128.pdf; KADI1124.pdf; image001.gif

Attached you will find the release attached for KADI1124 and KADI1128.

Please let me know the date of first use so I can submit them.

Thanks,

Cristina Garcia  
Regulatory Affairs Labeling Associate III

Actavis  
200 Elmora Avenue t +1 908-659-2323 @ [CGarcia@actavis.com](mailto:CGarcia@actavis.com) Elizabeth , NJ 07202 United States w [www.actavis.com](http://www.actavis.com)  
<<http://www.actavis.com/>> Internal VoIP number t 1202323

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From: Jennifer Altier [<mailto:jaltier2001@yahoo.com>]  
Sent: Thursday, August 11, 2011 12:13 AM  
To: Cristina Garcia  
Subject: KADIAN Approvals



Hi Cristina,

Please find attached the approval forms for 6 waves of direct mail for KADIAN (KADI1124, KADI1129-KADI1133) and the accompanying envelopes (KADI1128, KADI1152-KADI1156).

Over the next few weeks you will receive the printed samples for approval as they are completed. When you receive the samples, please use these forms to review and release them for use.

If you have any questions please let me know.

Thanks,

Jennifer

--- On Thu, 8/4/11, Arnetha Wharton <[AWharton@Actavis.com](mailto:AWharton@Actavis.com)> wrote:

From: Arnetha Wharton <[AWharton@Actavis.com](mailto:AWharton@Actavis.com)>

Subject: KADIAN Approvals

To: "Jennifer Altier" <[jaltier2001@yahoo.com](mailto:jaltier2001@yahoo.com)>

Cc: "Beth Zelnick-Kaufman" <[BZelnick-Kaufman@actavis.com](mailto:BZelnick-Kaufman@actavis.com)>, "Joann Stavole" <[JSTAVOLE@actavis.com](mailto:JSTAVOLE@actavis.com)>

Date: Thursday, August 4, 2011, 9:00 AM

Hi Jennifer,

Attached please find the approvals for the KADIAN advertisements and promotions sent July 31, 2011.

Thanks,

Arnetha

Arnetha Wharton  
Commercial Paralegal

Actavis

60 Columbia Rd. Bldg B t +1 973-889-6973 @ [AWharton@Actavis.com](mailto:AWharton@Actavis.com)

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Title:

ADVERTISEMENT & PROMOTION  
REVIEW/APPROVAL

Number:

FRA-003A

Review Date	August 1, 2011
Job Description	Wave #1 Direct Mail Program <i>Physician letter BSK 8/1/11</i>
Job Code	KADI1124
Target Audience	Physicians
Method of Delivery	U.S. Mail and Rep delivered
New or Revised	<input checked="" type="checkbox"/> New <input type="checkbox"/> Revised from Job Code _____ Comment:
Package Insert Required	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Leave Behind	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Template:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Comments	
DDMAC Submission Required	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

## PRC (Promotional Review Committee) Approval Sign Off

Print Name	Dept	Signature	Date
<i>Barbara Zelaich Kaufman</i>	Legal	<i>[Signature]</i>	8/1/11
<i>Jean Starnie</i>	Regulatory	<i>[Signature]</i>	08/01/2011
	Medical Consult*		
	Expert Consult*		

Amend and Re-circulate (Check box if applicable)

\*Indicate "not applicable" or "NA" in the signature space if consult not required for the piece.

## Marketing Sign-Off

Print Name	Signature	Date
<i>Jennifer Alter</i>	<i>[Signature]</i>	8/1/11
Approved		

## Regulatory Release Sign Off

Print Name	Signature	Date
<i>Cristina F. Garcia</i>	<i>[Signature]</i>	09/15/11



**KADIAN** CII

Morphine Sulfate  
Extended-Release Capsules

10mg - 20mg - 30mg - 50mg - 60mg - 80mg - 100mg - 200mg



Please consider prescribing KADIAN® (morphine sulfate extended-release) Capsules CII for your patients when appropriate.

Actavis is proud of KADIAN®'s 15-year history as an approved long-acting opioid.

- KADIAN® has formulary coverage for the majority of patients in the top 25 U.S. Health Plans.<sup>1</sup>
- Over 87% of KADIAN® patients with managed care coverage pay \$50 or less for their prescription.<sup>2</sup>
- The KADIAN® Co-Pay Assistance Program provides the first \$50 toward each prescription for up to 24 prescriptions over 12 months.



### Generic prescription co-pay costs vs KADIAN® co-pay costs

#### Generic Rx Co-Pay

2010 National Average  
for all Generic Rx Products

**\$6.06<sup>3</sup>**

#### KADIAN® Co-Pay Assistance Program

Over **87%** of KADIAN® patients  
with managed care coverage can pay

**\$0**

for their prescription after using the  
co-pay assistance card.<sup>2</sup>

To learn more about KADIAN® formulary coverage in your area or for Co-Pay Assistance Cards, contact your KADIAN® representative or call 1-800-216-1162.

**Rx only**

**WARNING:**

KADIAN® contains morphine sulfate, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. KADIAN® can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing KADIAN® in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

KADIAN® capsules are an extended-release oral formulation of morphine sulfate indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

KADIAN® Capsules are NOT for use as a prn analgesic.

KADIAN® 100 mg and 200 mg Capsules ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. Ingestion of these capsules or of the pellets within the capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids.

KADIAN® CAPSULES ARE TO BE SWALLOWED WHOLE OR THE CONTENTS OF THE CAPSULES SPRINKLED ON APPLE SAUCE. THE PELLETS IN THE CAPSULES ARE NOT TO BE CHEWED, CRUSHED, OR DISSOLVED DUE TO THE RISK OF RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE.

Please see accompanying Full Prescribing Information.

1. A/S Directory of Health Plans: 2011, Fingertip Formulary (T2 and T3), 2011, and Data on File at Actavis Elizabeth LLC.

2. Data on file at Actavis Elizabeth LLC., 1st Quarter 2011.


3. "The Use of Medicines in the United States: Review of 2010." IMS Institute for Healthcare Informatics study, April 2011

KADIAN® is a registered trademark of Actavis Elizabeth LLC.

KADI1124





	Title:	ADVERTISMENT & PROMOTION REVIEW/APPROVAL	Number:	FRA-003A

Review Date	July 12, 2011
Job Description	Direct Mail Wave #1 Envelope
Job Code	KADI1128
Target Audience	Healthcare Professionals
Method of Delivery	US Mail and sales rep delivery
New or Revised	<input checked="" type="checkbox"/> New <input type="checkbox"/> Revised from Job Code _____ Comment:
Package Insert Required	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Leave Behind	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Template:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Comments	
DDMAC Submission Required	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

PRC (Promotional Review Committee) Approval Sign Off

Print Name	Dept	Signature	Date
<i>Zeljka Zeluck Kaufman</i>	Legal	<i>Zeljka Zeluck Kaufman</i>	7/12/11
<i>Joann Stawik</i>	Regulatory	<i>Joann Stawik</i>	07/12/2011
	Medical Consult*		
	Expert Consult*		

Amend and Re-circulate (Check box if applicable)

\*Indicate "not applicable" or "NA" in the signature space if consult not required for the piece.

Marketing Sign-Off

Print Name	Signature	Date
<i>Jennifer Athier</i>	<i>Jennifer Athier</i>	7/12/2011
Approved		

Regulatory Release Sign Off

Print Name	Signature	Date
<i>Cristina F. Garcia</i>	<i>Cristina F. Garcia</i>	07/15/11



think smart medicine

Actavis Kadian LLC  
60 Columbia Rd., Bldg. B  
Morristown, NJ 07960 USA

*Help Your Long Acting  
Opioid Patients*

**Reduce or  
Eliminate**

*Their Prescription Costs!*



*9/8 07/2016*

ALLERGAN\_MDL\_01440044

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KAD1128