FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS
10903 NEW HAMPSHIRE AVE, BLDG #51
SILVER SPRING, MD 20993

FAX

Date: August 4, 2010

To: **Terri Nataline**
Vice President, Regulatory and Medical Affairs
Actavis US

Fax: **(973) 993-4303**

Phone: **(908) 659-2317**

From: Elaine Hu Cunningham, Pharm.D.,
CDR, United States Public Health Service
Senior Regulatory Review Officer
Phone: (301) 796-1200
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Subject: **NDA 020616 / MACMIS #18148**

Pages: **3** (not including cover sheet)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Terri Nataline
Vice President, Regulatory and Medical Affairs
Actavis US
60 Columbia Road, Building B
Morristown, NJ 07960

RE: NDA 020616
Kadian® (morphine extended-release) Capsules, CII
MACMIS #18148

Dear Ms. Nataline:

This letter responds to Actavis Elizabeth LLC's (Actavis) July 16, 2010, letter submitted to the Division of Drug Marketing, Advertising, and Communications (DDMAC) in response to DDMAC's July 6, 2010, letter requesting revisions to Actavis' June 10, 2010, proposed dissemination plan and finalized Dear Consumer and Dear Healthcare Provider (DHP) letters.

Reference is made to the February 18, 2010, DDMAC Warning Letter for Kadian® (morphine extended-release) Capsules, CII (Kadian). Further reference is made to Actavis' letters dated March 4 and 5, 2010, April 9, 2010, and May 3, 2010, and DDMAC's letters dated March 26, 2010, April 19, 2010, and May 20, 2010.

DDMAC has reviewed your July 16, 2010, submission, including a revised dissemination plan and finalized Dear Consumer and DHP letters. Reference is also made to a teleconference between DDMAC (Elaine Cunningham) and Actavis (Carla Hedrick) on August 4, 2010.

DDMAC has determined that the revised dissemination plan and Dear Consumer and DHP letters adequately address the issues raised in the Warning Letter and have no further comments at this time.

Please submit final copies of the Dear Consumer and DHP letters and envelope on Form FDA-2253 at the time of initial dissemination and submit written confirmation to DDMAC once dissemination of the Dear Consumer and DHP letters have been completed.

We remind you that the approved product labeling should accompany the Dear Consumer and DHP letters and the mailings should be done in accordance with 21 CFR 200.5, "Important Correction of Drug Information."

If you have any comments or questions, please contact me at the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, 5901-B Ammendale Road, Beltsville, MD 20705-1266, or by facsimile at (301) 847-8444.

If you choose to revise your promotional materials, DDMAC is willing to assist you with your revised materials by commenting on your revisions before you use them in promotion.

In all future correspondence regarding this matter, please refer to MACMIS #18148 in addition to the NDA number. We remind you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Elaine Hu Cunningham, Pharm.D.
CDR, United States Public Health Service
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20616	ORIG-1	ACTAVIS ELIZABETH LLC	KADIAN (MORPHINE SULFATE) ER CAPS 20/50

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ELAINE H CUNNINGHAM
08/04/2010