DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020616/S-048

SUPPLEMENT APPROVAL

Actavis Elizabeth, LLC
Regulatory Affairs Department
200 Elmora Avenue
Elizabeth, NJ 07207

Attention: Charlene Salmorin
Director, Labeling

Dear Ms. Salmorin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 2, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for KADIAN (morphine sulfate extended-release) Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, and 200 mg.

This "Changes Being Effected" supplemental new drug application provides for revised container labels for KADIAN 100 mg, 130 mg, 150 mg, and 200 mg, to include a flag that states, "**FOR USE IN OPIOID TOLERANT PATIENTS ONLY**."

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text for the container labels, submitted on January 2, 2013.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lisa Basham, Senior Regulatory Health Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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/s/

RIGOBERTO A ROCA on behalf of BOB A RAPPAPORT
03/27/2013