DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

REMS ASSESSMENT ACKNOWLEDGMENT FOR THE EXTENDED-RELEASE/LONG-ACTING (ER/LA) OPIOID REMS

c/o Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: Lisa Malandro, M.B.A.
Director, Worldwide Regulatory Strategy
REMS Program Companies (RPC) Liaison

To the Holders of the applications listed below:

Please refer to the following New Drug Applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA):

NDA 021260 AVINZA (morphine sulfate) extended-release capsules
NDA 021306 BUTRANS (buprenorphine) transdermal system
NDA 006134 DOLOPHINE (methadone HCl) tablets
NDA 019813 DURAGESIC (fentanyl transdermal system)
NDA 022321 EMBEDA (morphine sulfate/naltrexone HCl) extended-release capsules
NDA 021217 EXALGO (hydromorphone HCl) extended-release capsules
NDA 020616 KADIAN (morphine sulfate) extended-release capsules
NDA 019516 MS CONTIN (morphine sulfate) controlled-release tablets
NDA 200533 NUCYNTA ER (tapentadol) extended-release oral tablets
NDA 201655 OPANA ER (oxymorphone HCl) extended-release oral tablets
NDA 021610 OPANA ER (oxymorphone HCl) extended-release oral tablets
NDA 022272 OXYCONTIN (oxycodone HCl) controlled-release tablets

We also refer to the submissions that arrived between July 2, 2013 and July 9, 2013, containing the 12-month assessment of the extended-release and long-acting (ER/LA) opioid analgesics risk evaluation and mitigation strategy (REMS). This REMS uses a single, shared system for the elements to assure safe use and the REMS assessments.

After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete with the following comments:

1. We acknowledge that the REMS-compliant training began in March 2013, but also note that the number of prescribers completing the REMS-compliant training as of the data cutoff for this report is low. Develop and provide plans to increase the number of

prescribers completing the training so that the performance goals for the REMS-compliant training may be met.

2. Your request to modify the centralized call center to utilize an interactive voice mail/message retrieval system is acceptable. Update the REMS supporting document with the changes to the call center and submit it in a REMS correspondence to your application.

3. In future prescriber surveys, conduct an analysis of survey participants' percentage of correct responses on the key risk messages, stratified by professional degree as follows: doctor of medicine, doctor of osteopathy, nurse practitioner, and physician assistant; conduct a similar analysis stratified by prescribers' medical specialties.

4. In future prescriber and patient surveys, provide a frequency distribution of the number and percentage of survey participants who got 0, 1, 2, etc., correct responses across the total number of items for each given key risk message.

If you have any questions, call Mark Liberatore, Safety Regulatory Project Manager, at (301) 796-2221.

Sincerely,

{See appended electronic signature page}

Judith A. Racoosin, M.D., M.P.H.
Deputy Director for Safety
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

JUDITH A RACOOSIN
10/24/2013