DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

XX-XXX

APPLICATION HOLDER

Attention: CONTACT

Dear CONTACT:

Please refer to your new drug application (NDA) for DRUG NAME.

This letter is to inform you that the Agency has determined certain opioid products, including DRUG NAME, will be required to have Risk Evaluation and Mitigation Strategies (REMS), to ensure that the benefits of the drugs continue to outweigh the risks of: 1) use of certain opioid products in non-opioid-tolerant individuals; 2) abuse; and 3) overdose, both accidental and intentional. The REMS will include elements to assure safe use to ensure that prescribers, dispensers, and patients are aware of and understand the risks and appropriate use of these products.

We are mindful of the provisions in FDAAA that state that elements to assure safe use must be, among other things, commensurate with the specific serious risk listed in the labeling of the drug, not be unduly burdensome on patient access to the drug, and be designed to be compatible with established distribution, procurement, and dispensing systems. We are also aware that, with limited exceptions, FDAAA requires generic and innovator products to use a single shared system to implement the elements to assure safe use.

We recognize that putting together a workable REMS for these widely prescribed products will present certain challenges, and we have decided to invite all affected sponsors to a meeting to discuss how such a program can best be designed to manage the risks. We will also discuss what we see are the next steps in developing a REMS for this class of drugs.

The meeting will be held on March 3, 2009, at 3:30 PM at 10903 New Hampshire Avenue, Silver Spring, MD 20993, Building 22. Please send no more than two representatives from your company and arrive at least 30 minutes prior to the scheduled start of the meeting to allow time to be processed through security. Please provide FDA CONTACT with a list of those attending (FDA CONTACT EMAIL ADDRESS). Contact FDA CONTACT at XXX-XXX-XXXX with any questions pertaining to this meeting.

If you have any other questions pertaining to this application, call PROJECT MANAGER, Regulatory Project Manager, at XXX-XXX-XXXX.

Sincerely,

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research