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GENERAL ADVICE

APPLICANT NAME
ADDRESS

Attention: CONTACT NAME
TITLE

Dear CONTACT:

This letter is to inform you of the Agency's intention to require a Risk Evaluation and Mitigation Strategy (REMS) that includes immediate-release (IR), extended-release (ER), and long-acting (LA) opioid analgesics to ensure the benefits of these drugs continue to outweigh the risks of misuse, abuse, addiction, overdose, and death.

The Agency is currently considering the recommendations provided at the joint meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) held on May 3-4, 2016. For example, we are considering a single, shared system REMS for IR, ER, and LA opioid analgesics, as well as the potential elements of an "Opioid Analgesic REMS".

We recognize that developing a practicable REMS for these widely prescribed products involving numerous application holders will present challenges. We are mindful of the provisions in section 505-1 of the Food, Drug and Cosmetic Act (FDCA) 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, the statute requires generic and innovator products to use a single shared system to implement the elements to assure safe use.

We are inviting all potentially affected sponsors to a meeting to discuss the recommendations from the advisory committee members, the Agency's thinking regarding those recommendations, and potential strategies for developing an "Opioid Analgesic REMS" that includes IR, ER, and LA products.

Meeting Details:

Date: Wednesday, January 25, 2017

Time: 9:30 AM – 11:30 AM (Eastern)

Location*: Tommy Douglas Conference Center
10000 New Hampshire Avenue
Room 9201-C
Silver Spring, MD 20903

Contact Person: Georgiann Ienzi
Project Manager
Center for Drug Evaluation and Research
Food and Drug Administration
(301) 796-3515
Georgiann.Ienzi@fda.hhs.gov

Please provide Georgiann Ienzi with the name and contact information of the individual attending within 15 days of receipt of this letter. Due to space restrictions, the meeting is limited to one representative per company. Remote access instructions will be provided upon request for additional company representatives to participate in the meeting. Additional logistical information will be provided in advance of the meeting.

Finally, if you have any questions pertaining to this meeting you may contact Georgiann Ienzi.

Sincerely,

{See appended electronic signature page}

Sharon H. Hertz, M.D.
Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

****The location of this meeting changed between the time this letter was issued and when the meeting took place. The meeting was conducted at the Federal Research Center (FDA Headquarters) Building 2, Room 2047, 10903 New Hampshire Avenue, Silver Spring, MD 20993. The date, time, and contact person for the meeting remained unchanged.***