This was sent to the public account.

FDA-2013-P-1288
FDA-2013-P-1289

Thanks

Michelle L. Batts
Food and Drug Administration
Immediate Office of the Commissioner
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2013 NOV -5 A 11:48

From: Kylee Sunderlin [mailto:kjs@advocatesforpregnantwomen.org]
Sent: Tuesday, October 29, 2013 4:57 PM
To: Commissioner FDA; Woodcock, Janet; Throckmorton, Douglas C; Rappaport, Bob A
Cc: Lynn Paltrow
Subject: ER/LA Opioid Analgesic Labeling Changes (Time Sensitive Request)

Dear Dr. Hamburg, Dr. Woodcock, Dr. Throckmorton, and Dr. Rappaport:

In conjunction with medical and psychological researchers; treatment providers; reproductive health, drug policy, harm reduction, and criminal justice organizations throughout the country , National Advocates for Pregnant Women (NAPW) submitted a Citizen Petition and a Petition for Stay of Action to the FDA on October 8, 2013. These petitions request that the FDA refrain from implementing the NOWS-related labeling changes for ER/LA opioid analgesics, as announced on September 10, 2013, because they are medically inaccurate and pose significant consequences for maternal and fetal health. Although the petitions have not yet been posted online, their docket numbers are FDA-2013-P-1288 and FDA-2013-P-1289.

On Friday, October 25, 2013, the FDA approved Zohydro ER and announced that it would be the first ER/LA opioid analgesic to have the updated labeling. We are deeply concerned that the FDA is implementing the NOWS-related labeling changes without having considered petitioners' requested stay of action. The boxed warning, in particular, is unsupported by medical evidence, and is neither in the public interest or in the interest of justice.

Due to the urgency of the situation, NAPW requests that the FDA consider the petitions immediately, refrain from putting the NOWS-related warnings on Zohydro and all other ER/LA opioid analgesics, and meet with NAPW to discuss how harmful these changes will be for many pregnant women and their babies if they go into effect.

Sincerely,

Kylee Sunderlin

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