



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

October 24, 2013

National Advocates for Pregnant Women
Kylee Sunderlin
15 West 36th Street, Suite 901
New York, NY 10018

Dear Petitioner(s):

Your petition to the Food and Drug Administration requesting the Agency to refrain from implementing the FDA's neonatal opioid withdrawal syndrome (NOWS)-related labeling changes for extended-release and long-acting (ER/LA) opioid analgesics as announced on September 10, 2013, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1288/CP1, and it was filed on 10/24/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Karen Kennard".

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)