



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 06 2013

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

2013 SEP 11 A 10:51

Kasia J. Lipska, MD MHS
Silvio E. Inzucchi, MD
Yale University School of Medicine
Department of Internal Medicine
Section of Endocrinology and Metabolism
P.O. Box 208020
New Haven, CT 06520-8020

Re: Docket No. FDA-2013-P-0298

Dear Drs. Lipska and Inzucchi:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on March 12, 2013 (Petition). Your Petition requests that the Agency revise the prescribing label for metformin to remove the current creatinine-based contraindications, and instead rely on estimated glomerular filtration rate (eGFR) thresholds.

FDA has been unable to reach a decision on your Petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your Petition as soon as we have reached a decision on your request.

Sincerely

for Jane Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research