



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

March 12, 2013

Kasia J Lipska, MD MHS  
Instructor in Medicine  
Yale University School of Medicine  
Department of Internal Medicine  
Section of Endocrinology and Metabolism  
PO Box 208020  
New Haven, CT 06520-8020

Dear Dr. Lipska:

Your petition to the Food and Drug Administration requesting to revise the prescribing label for metformin. The revised label should remove the current creatinine-based contraindications, and instead rely on estimated glomerular filtration rate (eGFR) thresholds, was received by this office on 03/12/2013. It was assigned docket number FDA-2013-P-0298/CP1, and it was filed on 03/12/2013. 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 black ink, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega  
Administrative Proceedings Officer  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)