DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 5, 2016

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

Email: kasia.lipska@yale.edu

Dear Petitioner:

Your petition for reconsideration to the Commissioner of the Food and Drug Administration to request that the precautions section specifically recommend use of a lower dose of metformin (up to half maximum dose, i.e., up to 500 mg of metformin twice daily) and monitoring of renal function frequently (every 3 months) in patients with an eGFR between 30-45 mL/min/1.73m2, was received by this office on 5/4/2016.

It was assigned docket number FDA-2013-P-0298 and it was filed on 5/5/2016. 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,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)