



February 24, 2015

Michael Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the FDA immediately require the removal from the market of the oral form of the antifungal agent ketoconazole was received by this office on 2/24/2015.

It was assigned docket number FDA-2015-P-0578, and it was filed on 2/24/2015. 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, appearing to read "D Bigby", enclosed in a thin black rectangular border.

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