

Public Health Service

Food and Drug Administration Silver Spring MD 20993

June 21, 2018

Michael A. Carome, M.D. Director Public Citizen's Health Research Group 1600 20th Street NW Washington, DC 20006

Sent via email to: mcarome@citizen.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug require removal from the market of all medications containing febuxostat, which is currently marketed under the brand name Uloric was received by this office on 06/21/2018.

It was assigned docket number FDA-2018-P-2408. 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)