DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

August 26, 2019

William H. Carson, M.D.
President & CEO
Otsuka Pharmaceutical Development
& Commercialization, Inc.
508 Carnegie Center Drive
Princeton, NJ 08540

Sent via email to: William.Carson@otsuka-us.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration request that the FDA:

1. Determine that SAMS CA 60 mg should not be approved due to the potential for inappropriate prescribing to patients with ADPKD and can no longer serve as an RLD for an ANDA applicant

2. Refuse to approve any pending ANDA for a generic version of SAM SCA 60 mg

3. Suspend and withdraw the approval of any ANDA for a generic version of SAMSCA 60 mg.

Your submission was received by this office on 08/23/2019. It was assigned docket number FDA-2019-P-4002. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.08.26 12:48:48 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)