DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 16, 2020

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Sent via email to: DDeschaine@ebglaw.com and bscott@ebglaw.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requests the following:

1. Decline to approve the roxadustat NDA unless and until the applicant submits additional data demonstrating that the drug's safety risks do not outweigh its potential therapeutic benefit, i.e., when indicated for use in ND-CKD patients and DD-CKD patients who are stable on dialysis.

    a. To demonstrate roxadustat is adequately safe for use in ND-CKD patients, we request FDA require the applicant to conduct a head-to-head clinical trial that is adequately powered to demonstrate non-inferiority of roxadustat to the current standard of care on major adverse cardiovascular events and all-cause mortality.

    b. FDA should also require the applicant to submit for FDA's review a sub-analysis of all available data from the applicant's Phase III clinical program that evaluates all-cause mortality outcomes in DD-CKD patients who are stable on dialysis to ensure roxadustat is non-inferior to the standard of care.

2. Require an approved roxadustat label to bare a boxed warning if the risk for all-cause mortality, or major adverse cardiovascular events, is similar or worse in comparison to the current standard of care.

Your submission was received by this office on 11/13/2020 and was assigned docket number FDA-2020-P-2193. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the suitability petition for filing is a procedural matter and 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: 2020.11.16 13:57:56 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
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