Delia Ann Deschaine
Epstein Becker and Green, P.C.
1227 25th St. NW
Washington DC 20037

Bonnie I. Scott
Epstein Becker and Green, P.C.
1925 Century Park East
Suite 500
Los Angeles, CA 90067

May, 12, 2021

Re: Docket No. FDA-2020-P-2193

Dear Ms. Deschaine and Ms. Scott:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 13, 2020. Your petition requests that the Agency "decline to approve any New Drug Application (NDA) for roxadustat (FG-4592) unless and until the applicant submits additional data demonstrating that the potential safety risks of roxadustat do not outweigh its therapeutic benefit." Your petition also requests that the Agency require roxadustat's label bear a boxed warning to appropriately alert consumers and healthcare professionals to the drug's potential safety risks if roxadustat poses risks for all-cause mortality or major adverse cardiovascular events that are similar to, or greater than, those posed by the current standard of care.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2021.05.12 15:35:31 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research