

January 20, 2023

Dear Drs. Zeldes, Carome, and Wolfe,

Thank you for your letter to Dr. Cavazzoni, Director of the Center for Drug Evaluation and Research and Dr. Farrell, Director of the Division of Non-Malignant Hematology, regarding New Drug Application (NDA) 216951 for daprodustat. Your letter expresses concerns with daprodustat and other members of the oral hypoxia-inducible factor prolyl hydroxylase inhibitor class proposed for the treatment of anemia due to chronic kidney disease in adults not on dialysis and those on dialysis. In your letter you summarize publicly described risks of roxadustat, vadadustat, and daprodustat and urge FDA not to approve daprodustat or other drugs in the class.

We appreciate the information you have provided to us in your letter. In general, we cannot discuss pending applications due to a variety of federal statutes and regulations, including, among others, the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and FDA regulations (21 CFR 20.61(c); 21CFR 312.130(b); 21CFR 314.430(c) and (d)(I). However, please know that your letter has been shared with the relevant staff in the Division of Non-Malignant Hematology, Office of Cardiology, Hematology, Endocrinology and Nephrology, and Office of New Drugs for their careful consideration.

Thank you for writing and sharing your views and concerns.

Sincerely,

*Ann T. Farrell*

Ann T. Farrell, MD  
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Office of Cardiology, Hematology,  
Endocrinology and Nephrology  
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