

Yan Lei
Qilu Pharmaceutical (Hainan) Co., Ltd
No.273-A, Nanhai Avenue, National High-Tech Zone
Haikou, Hainan, 570314, China

November 19, 2024

Re: Docket No. FDA-2024-P-3482

Dear Yan Lei:

This letter responds to your citizen petition received on July 24, 2024, requesting that the Food and Drug Administration (FDA) determine whether JESDUVROQ (daprodustat) tablets, 1 milligram (mg); 2 mg; 4 mg; 6 mg; 8 mg, new drug application 216951, held by Glaxosmithkline Intellectual Property (No. 2) Limited England, were voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that JESDUVROQ (daprodustat) tablets, 1 mg; 2 mg; 4 mg; 6 mg; 8 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain JESDUVROQ (daprodustat) tablets, 1 mg; 2 mg; 4 mg; 6 mg; 8 mg, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-0110.

Sincerely,

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Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure