



Madhusudan Rao  
Chief Operating Officer  
BE Pharmaceuticals AG  
3 Bundesstrasse, Zug  
Canton of Zug, Switzerland – 6302

May 15, 2023

Re: Docket No. FDA-2022-P-2952

Dear Mr. Rao:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on November 18, 2022 (Petition). In the Petition, you request that FDA determine whether Heparin Sodium, injection, 5,000 United States Pharmacopeia (USP) units/milliliter approved by FDA under new drug application 017029 has been withdrawn from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your Petition because of the need to address other Agency priorities. 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 when we have reached a decision on your request.

Sincerely,

*nikki mueller*

Nikki Mueller  
Regulatory Counsel  
Office of Regulatory Policy  
Center for Drug Evaluation and Research