U.S. FOOD & DRUG ADMINISTRATION

Jennifer Boysen
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Docket No. FDA-2019-P-0466

JUL 25 2019

Dear Ms. Boysen:

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 January 29, 2019, and submitted on behalf of Fresenius Kabi USA, LLC. Your petition requests that the Agency determine whether the New Drug Application (NDA) 017521 for Dextrose, 20 grams (gm) /100 milliliters (mL), and Dextrose, 50gm/100mL (Dextrose 20%, and Dextrose 50%) in Plastic Containers was withdrawn for reasons of safety or efficacy.

FDA has been unable to reach a decision on your petition due to 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 soon as possible given the numerous demands on the Agency's resources.

Sincerely,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

bcc:
Division of Dockets Management / FDA-2019-P-0466
ORP/Petition File
Reading File
Heather A Dorsey
Lars Flores

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| Drafted: | H. Dorsey 7/22/19 |
| Reviewed/Cleared: | N. Hayes 7/22/19 |