Molly Ventrelli
Senior Vice President, Regulatory Affairs
Fresenius Kabi USA LLC
Three Corporate Drive
Lake Zurich, IL 60047

April, 23, 2021

Re: Docket No. FDA-2020-P-2133

Dear Ms. Ventrelli:

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 October 26, 2020. Your petition requests that the Agency: (1) refuse to file or approve any abbreviated new drug application (ANDA) or 505(b)(2) new drug application (NDA) for Levothyroxine Sodium Intravenous Solution that does not rely upon the reference listed drug (RLD) approved under NDA 210632; and (2) require that any such pending application be filed as a new ANDA or 505(b)(2) application and make all appropriate patent certifications with respect to the patents listed for NDA 210632.

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 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: 2021.04.23 09:38:53 -04'00'

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

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