**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

October 27, 2020

Molly Ventrelli
Fresenius Kabi USA LLC
Three Corporate Drive
Lake Zurich, IL 60047

Sent via email to: molly.ventrelli@fresenius-kabi.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA refuse to file or approve any Abbreviated New Drug Application (ANDA) or 505(b)(2) application for Levothyroxine Sodium Intravenous Solution that does not reference the Reference Listed Drug approved in NDA No. 210632 and require that any such pending applications be filed as a new ANDA or 0505(b)(2) application and make all appropriate certifications with respect to the patents listed for NDA No. 210632 was received by this office on 10/26/2020.

It was assigned docket number FDA-2020-P-2133. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.10.27 23:52:23 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)