DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 10, 2020

Scott Bass &
Emily Marden
Sidley Austin, LLP.
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Washington, DC 20005

Sent via email to: sbass@sidley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following two actions described below:

1) Asks that FDA issue guidance, and publicly affirm, that the ANDA approval pathway is not appropriate for harder-to-copy complex drugs already identified by FDA.

2) Vifor asks that FDA's planned guidance on therapeutic equivalence for follow-on drugs approved pursuant to Section 505(b)(2)4 make clear that a follow-on harder-to-copy complex drug may be determined to be therapeutically equivalent to its reference listed drug ("RLD"), when the two drugs meet the existing criteria, namely, they have: (1) the same active ingredient; (2) the same route of administration, dosage form, and strength; (3) the same clinical effect and safety profile; and (4) been shown to be bioequivalent.

This petition was received by this office on 01/09/2020 and it was assigned docket number FDA-2020-P-0158. 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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2020.01.10 12:53:54 -05'00'

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