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

Food and Drug Administration
Silver Spring MD 20993

July 25, 2019

Chad A. Landmon
Axinn
950 F Street, NW
Washington, DC 20004

Sent via email to: CLANDMON@AXINN.COM

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner take the following actions:

(1) To ensure bioequivalence between the RLD and ANDAs for Carbamazepine Extended Release Tablets, require pending and approved ANDAs to meet the rigorous bioequivalence standard that Zydus's ANDA has met by submitting a passing bioequivalence study with a fully replicated crossover design that has scaled bioequivalence limits to the variability of the reference product and compared the within subject variability of test and reference products, in compliance with the March 2015 Guidance;

(2) Downgrade the TE code of any approved ANDA currently listed as "AB" in the Orange Book to "BX" unless and until such a study has been provided to FDA;

(3) Assess whether the size and shape differences between approved ANDA products and the RLD pose patient safety and compliance issues; and

(4) Downgrade the TE code of any approved ANDA currently listed as "AB" in the Orange Book to "BX" if FDA concludes that the differences pose safety and compliance issues.

Your submission was received by this office on 07/24/2019, and it was assigned docket number FDA-2019-P-3545. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.07.26 08:23:41 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
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