NDA 205649/S-012

APPROVAL LETTER

AstraZeneca AB
c/o AstraZeneca Pharmaceuticals LP
Attention: Craig Zecher
Regulatory Affairs Director
1800 Concord Pike
Wilmington, DE 19803

Dear Mr. Zecher:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 12, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XIGDUO XR (dapagliflozin and metformin HCl extended-release) tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for Updates for metformin HCl and for metformin HCl + magnesium stearate in two DMFs, (b) (4):

- Addition of an alternative analytical method for the control of related substances by HPLC
- Deletion of the (b) (4) test from the specifications due to implementation of ICH Q3D on elemental impurities
- Implementation of (b) (4) testing (b) (4)

APPROVAL

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christopher LaFleur, Regulatory Business Process Manager, at (240) 402 - 4724.

Sincerely,

{See appended electronic signature page}

For:
Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

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