



NDA 020329/S-035

APPROVAL LETTER

Pfizer, Inc.
Attention: Nataly Zarate
Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Zarate:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 14, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Glucotrol XL (glipizide) Extended Release Tablets.

This “Changes Being Effectuated” supplemental new drug application provides for changes to the labeling based on the Agency’s Supplement Request Letter dated March 25, 2021 with the following revisions:

- Revision to the Assay acceptance criteria to (b) (4) % of the target amount including the overfill in each tablet
- Revision to the product labeling to clearly identify that each strength of the product contains overfill
- Revision to the Package Insert to include the same information about the total drug content (including the overfill) and the delivered amount

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling and with the minor editorial revisions listed below.

The revision date listed at the end of the Highlights of Prescribing Information has been updated to “8/2021.”

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on May 14, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020329/S-035.**” Approval of this submission by FDA is not required before the labeling is used.

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}

Ramesh Raghavachari, Ph.D.
Chief, Branch 1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

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Enclosures:

Content of Labeling

Carton and Container Labeling



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari
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