



NDA 017783/S-025

**SUPPLEMENT APPROVAL**

Pfizer Inc.  
Attention: Sheetal Alur, RPh, MS  
Senior Manager, Worldwide Regulatory Strategy  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Alur:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 18, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Glucotrol (glipizide) tablets 5 mg and 10 mg.

We also refer to our Prior Approval Supplement Request letter dated March 7, 2013, requesting additional revisions to the label for Glucotrol.

Supplemental new drug application, S-025, provides for the following revisions to the labeling for Glucotrol. Additions are noted by underline.

Under **PRECAUTIONS, Drug Interactions:**

In studies assessing the effect of colesevelam on the pharmacokinetics of glipizide ER in healthy volunteers, reductions in glipizide AUC<sub>0-∞</sub> and C<sub>max</sub> of 12% and 13%, respectively were observed when colesevelam was coadministered with glipizide ER. When glipizide ER was administered 4 hours prior to colesevelam, there was no significant change in glipizide AUC<sub>0-∞</sub> or C<sub>max</sub>, -4% and 0%, respectively. Therefore, GLUCOTROL should be administered at least 4 hours prior to colesevelam to ensure that colesevelam does not reduce the absorption of glipizide.

Under **DOSAGE AND ADMINISTRATION, Patients Receiving Other Oral Hypoglycemic Agents:**

When colesevelam is coadministered with glipizide ER, maximum plasma concentration and total exposure to glipizide is reduced. Therefore, GLUCOTROL should be administered at least 4 hours prior to colesevelam.

Under **HOW SUPPLIED:**

5 mg–Pfizer 411; 10 mg–Pfizer 412.

## **APPROVAL & LABELING**

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

Revised ~~March~~ October 2013

## **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 package insert), 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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).

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Raymond Chiang, Regulatory Project Manager, at (301) 796-1940.

Sincerely,

*{See appended electronic signature page}*

Amy G. Egan, M.D., M.P.H.  
Deputy Director for Safety  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE:  
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/s/  
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AMY G EGAN  
10/15/2013