DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020682/S-010

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Sheetal Alur, RPh, MS
Worldwide Regulatory Affairs
235 East 42nd Street
New York, New York 10017-5755

Dear Ms. Alur:

Please refer to your Supplemental New Drug Application (sNDA) dated December 2, 2011, received December 2, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Glyset (miglitol) Tablets, 25 mg, 50 mg and 100 mg.

We acknowledge receipt of your amendment dated August 22, 2012.

This Prior Approval sNDA, submitted in response to our supplement request letter dated October 14, 2011, provides for addition of information to the **ADVERSE REACTIONS** section regarding pneumatosis cystoides intestinalis associated with use of alpha-glucosidase inhibitors. In addition to this change we requested, this sNDA also provides for the following:

1. Addition of language to the **CLINICAL PHARMACOLOGY** section, under **Special Populations, Renal Impairment.**
2. Addition of language to the **PRECAUTIONS** section, under **Hyperglycemia**.
3. Addition of language to the **ADVERSE REACTIONS** section regarding gastrointestinal disorders.

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.

We note that your August 22, 2012, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 Effected" (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 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).

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, please call Ms. Jena M. Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE: Package insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY H PARKS
09/17/2012