DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-682/S-008

Pfizer Global Pharmaceuticals
Attention: Kathleen Collins
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, New York 10017

Dear Ms. Collins:

Please refer to your supplemental new drug application dated September 18, 2008, received September 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for GLYCET (miglitol) Tablets.

We acknowledge receipt of your submission dated September 19, 2008.

This supplemental new drug application provides for labeling revisions to the **CLINCAL STUDIES, INDICATIONS AND USAGE** and **PRECAUTIONS** sections of the package insert as requested in our letter dated November 20, 2007. We also acknowledge editorial changes.

We have completed our review of this application, as amended. This application is **approved**, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. We note that this submission included content of labeling in structured product labeling (SPL) format.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & 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 Parks

4/24/2009 10:46:28 PM