DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 20-329/S-002

Pfizer Inc.
Attention: John P. Kennedy
Associate Director
235 East 42nd Street
New York, NY 10017-5755

Dear Mr. Kennedy:

Please refer to your supplemental new drug application dated November 2, 1998, received November 3, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glucotrol® XL (glipizide) Extended Release Tablets.

We acknowledge receipt of your submissions dated March 28, 2001 and March 13, 2002. Your submission of March 13, 2002 constituted a complete response to our December 14, 2000 action letter.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. The enclosed labeling text incorporates the revisions of this supplement into the labeling from supplement-013, approved on October 26, 2001 (Identifier: 69-4952-00-6, Revision date: April 2001). In addition, to comply with the FDA guidance entitled, *Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements* (Issued 7/1998), the "Rx only" symbol should be located in the title section of the package insert. The supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed text for the package insert.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-329/S-002." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call James Cross, Regulatory Project Manager, at 301-827-6381.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

David Orloff

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