DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-641/S-061

Pfizer Inc.
Attention: Marianne Kopelman
Director, Worldwide Regulatory Strategy
235 East 42nd Street
NY, NY 10017

Dear Ms. Kopelman:

Please refer to your supplemental new drug application dated December 17, 2002, received December 18, 2002, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Diabinese® (chlorpropamide) Tablets.

We acknowledge receipt of your submission dated December 30, 2002.

This "Special Supplement – Changes Being Effected" supplemental new drug application provides for the revision of the package insert to include post-marketing adverse reactions.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 17, 2002. However, we have the following comments and requests for additional information. Written response is requested.

1. The **PRECAUTIONS**, **General**, *Hypoglycemia* section of the revised package insert states, "Renal and hepatic insufficiency may affect the disposition of DIABINESE . . .". Please provide justification for this statement.

2. The **PRECAUTIONS**, **General**, *Hypoglycemia* section of the revised package insert states, "Renal and hepatic insufficiency may affect the disposition of DIABINESE and the latter may also diminish gluconeogenic capacity, both of which increase the risk of serious hypoglycemic reactions." Both renal and hepatic insufficiency may diminish gluconeogenic capacity. We recommend you remove "the latter" from this statement at the next printing so that the statement would be as follows: "Renal and hepatic insufficiency may affect the disposition of DIABINESE and may also diminish gluconeogenic capacity, both of which increase the risk of serious hypoglycemic reactions."

3. Of note, Diabinese is misspelled a few times throughout the package insert.

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, HFD-410
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.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. To expedite review of this patent declaration form, we request you submit an additional copy of the form to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

If you have any questions, please call Lina AlJuburi, Regulatory Project Manager, at (301) 827-6414.

Sincerely,

{See appended electronic signature page}

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

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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