DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 11-641/S-058
NDA 11-641/S-060

Pfizer Inc.
Attention: Michelle Campbell, R.Ph.
Director, Worldwide Regulatory Strategy
235 E. 42nd Street 150/7/12
New York, NY 10017

Dear Ms. Campbell:

Please refer to your supplemental new drug applications submitted August 2, 1999 (S-058), and May 23, 2001 (S-060), received August 3, 1999, and May 24, 2001, respectively, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diabinese® (chlorpropamide) Tablets, USP.

We acknowledge receipt of your submissions dated June 4, 2001 (S-060) and June 19, 2001 (S-058).

Supplement–058 provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section of the package insert. Supplement–060 provides for revisions to the *Carcinogenesis, Mutagenesis, and Impairment of Fertility* paragraph of the **DRUG INTERACTIONS** section of the package insert.

We have completed the review of these supplemental applications, 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 submitted final printed labeling (package insert submitted April 16, 2002). Accordingly, these supplemental applications are approved effective on the date of this letter.

Note: Section 126 of Title I of the 1997 Food and Drug Administration Modernization Act amends section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(4)) to require, at a minimum, that the label of prescription products contain the symbol "Rx only." According to 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 is not required for package insert labeling, if located on the carton/container labeling. However, should a manufacturer choose to include the symbol, the Agency prefers that the symbol be located in the title section. The "Rx only" symbol for this package insert is located at the end of the HOW SUPPLIED section of the package insert, rather than at the beginning. the "Rx only" symbol should be relocated to the title section of the package insert. This can be implemented at the next printing and the Agency notified in the annual report.

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

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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