CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020682/S001

Trade Name: GLYSET TABLETS 25mg, 50mg, and 100mg

Generic Name: MIGLITOL

Sponsor: PHARMACIA and UPJOHN

Approval Date: 08/16/99

INDICATION(s): AS AN ADJUNCT TO DIET TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH NON-INSULIN-DEPENDENT DIABETES MELLITUS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 020682/S01

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling				X
Medical Review(s)				X
Chemistry Review(s)				X
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative/ Correspondence Document(s)	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020682/S001

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-682/S-001

Pharmacia & Upjohn
Attention: Cynthia Blanchard
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

AUG 16 1999

Dear Ms. Blanchard:

Please refer to your supplemental new drug application dated August 18, 1998, received August 19, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glyset® (miglitol) Tablets, 25 mg, 50 mg and 100 mg.

This supplemental new drug application provides for the addition of a Geriatric Use subsection to the **PRECAUTIONS** section of the package insert per 21 CFR 201.57(f)(10)(ii)(B).

We have completed the review of this supplemental application 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 draft labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (text for the package insert dated August 18, 1998).

Please submit 20 copies of the FPL as soon as it is available, in no case 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 20-682/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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, please contact Ms. Jena Weber, Regulatory Project Manager, at (301) 827-6422.

Sincerely,

/S/

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

APPEARS THIS WAY ON ORIGINAL