DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 24 1997

TRANSMITTED VIA FACSIMILE

James A. Parker, Jr.
Director, Advertising and Labeling
Worldwide Regulatory Affairs
Parke-Davis Pharmaceutical Research
Division of Warner-Lambert Company
201 Tabor Road
Morris Plains, NJ 07950

RE: **NDA#** 20-720
Rezulin (troglitazone) Tablets
MACMIS ID #5121

Dear Mr. Parker:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Rezulin (troglitazone) tablets that are considered violative of the Federal Food, Drug, and Cosmetic Act. DDMAC specifically refers to the press release issued by Warner-Lambert Company on January 30, 1997, announcing the approval of Rezulin (troglitazone) that contains the following statements:

"Rezulin is the first antidiabetes drug designed to target insulin resistance..." and "Rezulin is the first drug to work at the cellular level to improve insulin resistance directly-enhancing the effects of circulating insulin... Until now, other therapies lowered blood glucose by increasing insulin production or decreasing hepatic glucose output."

DDMAC considers these statements to be false and misleading because Rezulin, while possessing a different mechanism of action than other antihyperglycemic agents, is not the first oral antihyperglycemic that reduces insulin resistance. Further, there are other approved therapies for Non Insulin Dependant Diabetes Mellitus with mechanisms of action other than by increasing insulin production or decreasing hepatic glucose output.

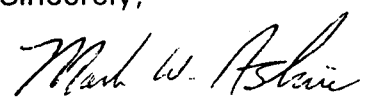
In addition, DDMAC has no record that Parke-Davis submitted this promotional labeling at the time of initial dissemination under Form FDA 2253. Such submissions are required by 21 C.F.R. 314.81 (b) (3) (i).

In order to address these concerns, DDMAC recommends that Parke-Davis immediately discontinue the publication and/or dissemination of the referenced piece and any other similar pieces containing the same or similar claims. DDMAC also requests that Parke-Davis respond to this letter, in writing, by March 6, 1997. Parke-Davis' response should include a list of all pieces that will be discontinued as well as completed FDA Form 2253's for all pieces that have not been submitted to the Agency pursuant to the post-marketing reporting requirements.

If Parke-Davis has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Parke-Davis that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5121 in addition to the NDA number.

Sincerely,



Mark W. Askine, R.Ph.
Regulatory Review officer
Division of Drug Marketing,
Advertising, and Communications

File Name: Reznov.let

Drafted: Askine	Date: 2/18/97
Comment: Rumble	Date: 2/18/97
Revised: Askine	Date: 2/18/97
Concur: Palmer	Date: 2/22/97
Comment: O'Brien	Date: 2/24/97
Revised: Askine	Date: 2/24/97

CC:
HFD-40/NDA # 20-720
HFD-40/Chron/Askine/Palmer/O'Brien
HFD-510/Misbin/Johnston/Fleming
HFD-510/NDA # 20-720

MACMIS ID #5121

MACMIS Type Code:LETT
MACMIS Action Code:VIOL

Due Date: March 6, 1997
Close Out: NO

FOI Status: Releasable