LIPHA PHARMACEUTICALS
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Dec. 29, 1994

VIA FAX AND FEDERAL EXPRESS
ACKNOWLEDGMENT OF RECEIPT REQUESTED

Food and Drug Administration
CDER, HFD-510
Attention: Document Control Room #14B-04
5600 Fishers Lane
Rockville, MD 20857

Attention: Solomon Sobel, M.D., Director
Division of Metabolism and Endocrine Drug Products

Reference: NDA #20-357 Metformin HCl Oral/Amendment #38

Dear Dr. Sobel:

Reference is made to our New Drug Application for Metformin Hydrochloride Oral (#20-357), submitted to the FDA on September 29, 1993.

In accord with our telephone conference of December 29, 1994 with Capt. John Short, we agree that Glucophage® will not be marketed in the United States without an accompanying Patient Package Insert (PPI). The language of this PPI will be mutually agreed upon by FDA and Lipha Pharmaceuticals, Inc. in the immediate future. This PPI will accompany the trade package of 100 tablets. If a larger bulk package is provided for in the NDA, a mechanism will be mutually agreed upon and implemented so that each patient will be provided with a copy of the PPI.

If there are questions relative to any of the above, please do not hesitate to contact this office.

Sincerely yours,

LIPHA PHARMACEUTICALS, INC.

Gerard L. Daniel, M.D.
Chairman, President &
Chief Executive Officer

GLD/AMG