



FILE COPY

August 27, 2003

Robert W. Pollock, Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

Dear Mr. Pollock:

Your petition requesting the Food and Drug Administration to declare that the drug product, Metformin Hydrochloride Extended-Release (XR) Tablets, 1000 mg is suitable for submission as an abbreviated new drug application, was received by this office on 08/27/2003. It was assigned docket number 2003P-0388 and it was filed on 08/27/2003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink that reads "Lyle D. Jaffe".

Lyle D. Jaffe
Division of Dockets Management

2003P-0388

ACK 1