DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 27 2003

Roberta Loomar
Andrx Pharmaceuticals, Inc.
4955 Orange Drive
Fort Lauderdale, FL 33314

Re: Docket No. 02P-0426/CP1

Dear Ms. Loomar:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on September 26, 2002. Your petition requests that the Agency determine that Andrx, in its currently pending ANDA 76-159 (glipizide extended release tablets, 10 mg), will not be required to file a new certification or amend its current Paragraph I Certification with respect to U.S. Patent No. 6,361,795 (the '795 Patent) or a reissued version of the '795 patent in the event a reissue of the '795 patent is subsequently listed in the Orange Book.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

02P-0426 LET 1