DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-574/S-005

Andrx Labs L.L.C.
Attention: Samuel Swetland
Manager, Regulatory Affairs
4955 Orange Drive
Ft. Lauderdale, FL 33314

Dear Mr. Swetland:

Please refer to your supplemental new drug application dated August 5, 2005, received August 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fortamet® (metformin HCl extended-release tablets) 500 mg and 1000 mg.

We acknowledge receipt of your submissions dated January 30, and February 7, 2006.

This supplemental application, submitted as "Supplement - Changes Being Effected," proposes to add a statement to the sample cartons to strengthen the Warnings statement by referring to the boxed warning in the full prescribing information. Additional editorial changes have also been specified.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the immediate sample cartons) submitted February 7, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-574/S-005**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Acting Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks

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