DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-574/S-006

Andrx Labs, L.L.C. (d/b/a Watson Laboratories – Florida)
Attention: Kemi Y. Onayemi, Ph.D.
Specialist, Regulatory Affairs
4955 Orange Drive
Ft. Lauderdale, FL 33314

Dear Dr. Onayemi:

Please refer to your supplemental new drug application dated March 22, 2007, received March 23, 2007, 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 submission dated April 3, 2007.

This supplemental application, submitted as "Supplement - Changes Being Effected" proposes revisions to the **CONTRAINDICATIONS, DOSAGE AND ADMINISTRATION** and **STORAGE** sections of the package insert, editorial changes, and revisions to the patient package insert.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 3, 2007.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (text for the package insert and patient package insert submitted April 3, 2007). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Submit final printed labeling (FPL) in electronic format that is identical to the enclosed labeling as soon as it is available. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-574/S-006**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you that you must comply with the 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.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE (package insert/patient package insert)

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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