DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-574

Andrx Labs, Inc.
Attention: Nicholas J. Farina, Ph.D.
Vice President, Regulatory Affairs
401 Hackensack Avenue, 9th Floor
Hackensack, NJ 07601

Dear Dr. Farina:

Please refer to your new drug application (NDA) dated December 17, 2002, received December 19, 2002, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fortamet (metformin extended-release) Tablets, 500 mg and 1000 mg.

We acknowledge receipt of your submissions dated December 19, 2003, and February 9, and 18, 2004. The December 19, 2003, submission constituted a complete response to our October 17, 2003, action letter.

We completed our review of this application as submitted with draft labeling, and it is **approvable**. Before the application may be approved, however, it will be necessary for you to provide the appropriate patent certifications.

Fortamet is an extended-release metformin tablet, as is Bristol-Myers Squibb's Glucophage XR. Glucophage XR was approved prior to your NDA submission. Fortamet and Glucophage XR are pharmaceutical equivalents (have the same active ingredient, dosage form, strength, route of administration). Section 505(j) of the Federal Food, Drug and Cosmetic Act provides a procedure for approval of generic drug products that, among other things, have the same active ingredient, dosage form, strength, and route of administration as the innovator product, through the abbreviated new drug application process. This process requires that the applicant provide certifications to patents for the listed drug the applicant proposes to duplicate. To prevent applicants from using the 505(b)(2) process to avoid these statutory patent certification requirements, FDA has interpreted section 505(b)(2)(A) to require certifications for any patents listed for pharmaceutical equivalents. This interpretation is described in FDA's *Draft Guidance for Industry: Applications Covered by Section 505(b)(2)* (October 1999) which states that "[i]f there is a listed drug that is the pharmaceutical equivalent of the drug proposed in the 505(b)(2) application, the 505(b)(2) application should provide patent certifications for the patents listed for the pharmaceutically equivalent drug." Because of the statutory requirement, your 505(b)(2) NDA must contain patent certifications for those patents listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for Glucophage XR (NDA 21-202).

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager at 301-827-6422.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II Center for Drug Evaluation

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

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/s/

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Mary Parks
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for Dr. Orloff