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 January 17, and 29, March 17, and 28, April 16, May 15, July 28, and September 30, 2003.

We completed our review of this application, as amended, and it is **approvable.** Before the application may be approved, however, it will be necessary for you to provide sufficient data to demonstrate dosage form equivalence between the 500 mg and 1000 mg tablets.

In addition, it will be necessary for you to submit revised labeling with the revisions indicated in the enclosed labeling. We are providing the following comments regarding your revisions:

- Revise the language under **CLINICAL PHARMACOLOGY** section, **Pharmacokinetics and Drug Metabolism** subsection, **Immediate-Release** subsection.
- [ ]
- [ ]
- [ ]
- [ ]
- Under **INDICATIONS AND USAGE section:** Reference to [ ] should be deleted.

- [redacted]

- Under **DOSAGE AND ADMINISTRATION** section: Revise language.

[redacted]

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

Submit revised labeling that incorporates the changes indicated in the enclosed labeling. A marked-up or highlighted copy as well as a clean copy of the labeling should be provided.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division, The Division of Metabolic and Endocrine Drug Products, HFD-510, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 and Research

ENCLOSURE (draft labeling)

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

/s/

David Orloff
10/17/03 01:15:44 PM