



NDA 21-574

Andrx Labs, Inc.  
Attention: Josephine Cucchiaro, Ph.D.  
Vice President, Regulatory Affairs  
401 Hackensack Avenue, 9<sup>th</sup> Floor  
Hackensack, NJ 07601

Dear Dr. Cucchiaro:

Please refer to your new drug application (NDA) dated December 17, 2002, received December 19, 2002, 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 February 26, and April 14, 19, and 22, 2004.

The February 26, 2004, submission constituted a complete response to our February 20, 2004, action letter.

This new drug application provides for the use of Fortamet (metformin HCl) Extended-Release Tablets as an adjunct to diet and exercise to lower blood glucose in patients with type 2 diabetes mellitus.

We completed our review of this application, as amended. It 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 labeling (text for the package insert and patient package insert) submitted April 27, 2004, and immediate carton and container labels (submitted February 9, 2004). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-574.**” 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 deferring submission of your pediatric studies for ages 10 to 16 years until December 31, 2004.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

Deferred pediatric study under PREA for the treatment of pediatric patients with type 2 diabetes mellitus in ages 10 to 16 years of age. Final Report Submission: December 31, 2004.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated “**Required Pediatric Study Commitments.**”

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, 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

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 301-827-6422.

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

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/

-----  
David Orloff

4/27/04 05:02:24 PM