



NDA 13-718/S-022

Bio-Technology General Corp.  
Attention: Briti Kundu  
Director, Regulatory Affairs  
70 One Tower Center, 14<sup>th</sup> Floor  
East Brunswick, NJ 08816

Dear Ms. Kundu:

Please refer to your supplemental new drug application dated April 19, 2002, received April 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxandrin (oxandrolone, USP) Tablets.

We acknowledge receipt of your submissions dated July 11 and October 18, 2002 and March 6, 2003. Your submission of October 18, 2002 constituted a complete response to our October 11, 2002 action letter.

This supplemental new drug application provides for the inclusion of information in the package insert regarding a drug interaction between oxandrolone and warfarin.

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 March 6, 2003.

We encourage you to issue a communication notifying health care professionals about this drug interaction.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kati Johnson, Supervisor, Project Management Staff, at (301) 827-6380.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD  
Director  
Division of Metabolic & Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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David Orloff

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