DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 5 2006

David G. Greene
Lord, Bissell & Brook LLP
885 Third Avenue
26th Floor
New York, NY 10022-4802

Re: Docket No. 2006P-0102/CP1

Dear Mr. Greene:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on March 8, 2006. Your petition requests that the Agency take appropriate remedial action relating to an apparent safety issue regarding the unapproved drug product Bellatal Extended Release (ER) manufactured by Anabolic, Inc. for Qualitest Pharmaceuticals, Inc.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0102

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