



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

SEP 20 2013

Benjamin J. Del Tito, Jr., Ph.D.
Executive Vice-President,
Regulatory Affairs & Project Management
Auxilium Pharmaceuticals, Inc.
640 Lee Road
Chesterbrook, PA 19087

Re: Docket No. FDA-2013-P-0371


Dear Dr. Del Tito:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 26, 2013. Your petition makes several requests related to the therapeutic equivalence rating for and labeling of the testosterone gel product that is the subject of new drug application 204399, submitted by Upsher-Smith Laboratories, 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,

A handwritten signature in blue ink, appearing to read "Jane A. Axelrad", is written over the typed name.

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