



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 26, 2013

FILE COPY

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

Dear Dr. Del Tito:

Your petition to the Food and Drug Administration requesting FDA to take action described in Section A of the petition with respect to therapeutic equivalence rating and labeling of the section 505(b)(2) application filed by Upsher-Smith Laboratories, Inc. ("USL"), No. 204399, for testosterone transdermal gel, 1%, was received by this office on 03/26/2013. It was assigned docket number FDA-2013-P-0371/CP1, and it was filed on 03/26/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Gloria Ortega", is written over a horizontal line.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)