DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-454
Auxilium
Attention: Diane Myers
Director, Regulatory Affairs
Norriton Office Center
160 W. Germantown Pike, Suite D-5
Norristown, PA 19401

Dear Ms. Myers:

Please refer to your New Drug Application (NDA) submitted on December 31, 2001, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Testim 1% (testosterone gel) 50 mg and 100 mg and approved on October 31, 2002.

Although the NDA was submitted as a 505(b)(2) application, it was determined that it was submitted under 505(b)(1). The literature cited in the NDA did not contain investigations necessary to approval of the NDA. Published, non-proprietary non-clinical information about testosterone is widely available and is sufficient to support approval. In addition, testosterone has been used in humans for many years and there is a vast body of knowledge associated with this use. Thus, the determination that Testim is safe and effective for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone is based, in the areas of non-clinical pharmacological actions, safety pharmacology, toxicology, genetic toxicology, reproductive and fetal effects, carcinogenicity, or the absorption, distribution, metabolic, and excretion characteristics of testosterone, solely on non-proprietary information. The non-proprietary information is found in available literature, and is derived from the general body of professional knowledge of reviewers of the application. The balance of the studies supporting safe and effective use of Testim as described above and necessary for approval were conducted or sponsored by Auxilium Pharmaceuticals.

If you have any questions, please call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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