CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200740Orig1s000

OTHER ACTION LETTERS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200740

COMPLETE RESPONSE

Sigma-Tau Pharmaceuticals, Inc.
Attention: Gianfranco Fornasini, Ph.D.
Senior Vice President, Scientific Affairs
9841 Washingtonian Blvd. Suite 500
Gaithersburg, MD 20878

Dear Dr. Fornasini:

Please refer to your New Drug Application (NDA) dated March 04, 2010, received March 04, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cystaran (cysteamine hydrochloride ophthalmic solution) 0.44%.

We acknowledge receipt of your amendments dated March 12 and 29, April 9 and 26, May 6, 13, 14, 20, 25 and 27, June 29, July 2, 12, 13, 14, 19, 20, 28, 29 and 30, August 6, 9, 24, 30, and 31, 2010.

We have completed our review of this application, and have determined that we cannot approve this application in its present form. We have described our reason for this action below and our recommendation to address this issue.

Manufacturing facilities for the drug substance and the drug product are not in compliance with current good manufacturing practice. Satisfactory resolution of this deficiency is required before this application may be approved. Please amend the application with facilities that are in compliance with current good manufacturing practice (cGMP) or notify us when all currently submitted facilities are in compliance with cGMPs. When you respond to the above deficiency, please include a safety update as described at 21 CFR 314.50(d)(5)(vi)(*b*).

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application. A resubmission must fully address the deficiency listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants," May 2009 at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Fariba Izadi, Pharm.D., Regulatory Health Project Manager at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200740	ORIG-1	SIGMA TAU PHARMACEUTICALS INC	(Cysteamine hydrochloride ophthalmic solution) 0.65% Sterile

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

/s/

WILEY A CHAMBERS
09/03/2010