DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018513/S-012 **SUPPLEMENT APPROVAL**

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

Dear Dr. Fornasini:

Please refer to your supplemental new drug application dated October 7, 2009, received October 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Chenix® (chenodiol) 250 mg Tablets.

We acknowledge receipt of your submissions dated October 7 and 23, of 2009.

This "Prior Approval" supplemental new drug application proposes a proprietary trade name change to Xenbilox.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 7, 2009, submission containing final printed carton and container labels.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

1. We note that the established name is at least ½ the size of the proprietary name, but it lacks prominence commensurate with the proprietary name. Increase the prominence of the established name taking into account all pertinent factors, including typography, layout, contrast, and other printing features in accordance with 21 CFR 201.10(g)(2).
2. The fragmented letter 'O' in the trade name may be misinterpreted as the letter 'v'. Additionally, presenting the name in two different font colors unduly emphasizes the "bilox" portion of the name. Revise the presentation of the trade

name so that the entire name is presented in the same font color and all letters are in the same font type.

3. We note the dosage form is located after the statement of strength. Relocate the statement of strength after the dosage form which is the customary position for this information.
4. We note the strength appears in a green font. Directly below the strength the net quantity appears in a highlighted green block. Using green coloring for both the strength and the net quantity does not provide distinction of the different pieces of information. Also, color blocking the net quantity gives more prominence to this statement rather than the strength. Remove the green color block and present the net quantity in black font to de-emphasize the net quantity.

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 018513/S-012**." Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

If you have any questions, call Hee (Sheila) Lianos, Regulatory Project Manager, at (301) 796 - 4147.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Division Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18513	SUPPL-12	SIGMA TAU PHARMACEUTICALS INC	CHENIX(CHENODIOL) TABS

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

/s/

DONNA J GRIEBEL
05/20/2010