DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22118/S-005

SUPPLEMENT APPROVAL

Santarus, Inc.
Attention: David Truong, PharmD
Manager, Regulatory Affairs
3721 Valley Centre Drive, Suite 400
San Diego, CA 92130

Dear Dr. Truong:

Please refer to your Supplemental New Drug Application (sNDA) dated October 23, 2012, received October 24, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FENOGLIDE (fenofibrate) Tablets, 40 and 120 mg.

This "Prior Approval" supplemental new drug application, submitted in response to our October 15, 2012 supplement request letter sent to sponsors of marketed fenofibrate products, provides for the following revisions to the package insert:
-Modification of the WARNINGS AND PRECAUTIONS section to include results from the ACCORD Lipid trial.
-Revision of the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections to include information on paradoxical decreases in HDL in patients taking fenofibrates
-Revision of the WARNINGS AND PRECAUTIONS and DRUG INTERACTION sections to state that cases of myopathy, including rhabdomyolysis, have been reported in patients taking fenofibrates co-administered with colchicine.

We have also revised the label to correct some formatting errors and to harmonize with other approved fenofibrate products.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Amy G. Egan, M.D., M.P.H.
Deputy Director for Safety
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AMY G EGAN
10/31/2012