DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-849

Santarus, Inc.
Attention: Christine Miller, PharmD
Vice President, Regulatory Affairs and Quality Assurance
10590 West Ocean Air Drive, Suite 200
San Diego, California 92130

Dear Dr. Miller:

Please refer to your new drug application (NDA) dated April 26, 2005, received April 27, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ZEGERID® (omeprazole/sodium bicarbonate) Capsules 20mg/1100mg and 40 mg/1100mg.

We acknowledge receipt of your submissions dated July 7, July 15, August 10, August 23, November 1, November 21, December 8, 2005, January 4, January 30, February 10, February 16, and February 23, 2006.

This new drug application provides for the use of ZEGERID® (omeprazole/sodium bicarbonate) Capsules 20mg for:

- Short-term treatment of active duodenal ulcer;
- Treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD);
- Short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy; and,
- Maintenance of healing of erosive esophagitis (EE).

ZEGERID® (omeprazole/sodium bicarbonate) Capsules 40 mg for:

- Short-term treatment (4-8) weeks) of active benign gastric ulcer.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels) and submitted labeling (package insert, immediate container and carton labels submitted February 16, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies

of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-849**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submission dated February 23, 2006. This commitment is listed below.

A study consisting of expanded dissolution testing using the USP Apparatus (b)(4) incorporating both (b)(4) minute sampling time points, for all lots manufactured during the first six months after approval, according to the following study schedule:

Protocol Submission:	by March 31, 2006
Study Start:	by May 1, 2006
Final Report Submission	by December 31, 2006

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing , and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report",** or **"Postmarketing Study Commitment Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to Division of Gastroenterology Products and two copies of both the promotional materials and the package insert directly to:

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

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Mary Lewis, Regulatory Project Manager at 301-796-0941.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joyce Korvick
2/27/2006 04:01:31 PM
for Dr. Brian E Harvey