CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-850

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-850

Santarus, Inc.
Attention: Charles H. Davis, RAC
Senior Director, Regulatory Affairs
10590 West Ocean Air Drive, Suite 200
San Diego, California 92130

Dear Mr. Davis:

Please refer to your new drug application (NDA) dated May 25, 2005, received May 26, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ZEGERID® with Magnesium Hydroxide (omeprazole/sodium bicarbonate/magnesium hydroxide) Chewable Tablets, 20mg/600mg/700mg, and 40mg/600mg/700mg.

We acknowledge receipt of your submissions dated July 25, August 29, September 21, September 30, December 15, 2005, January 12, March 1, March 7, March 8, March 9, March 14, March 15, March 17, March 20, March 22, March 23, and March 24, 2006.

This new drug application provides for the use of ZEGERID® with Magnesium Hydroxide (omeprazole/sodium bicarbonate/magnesium hydroxide) 20mg/600mg/700mg and 40mg/600mg/700mg for the following indication:

ZEGERID® with Magnesium Hydroxide 20mg Chewable tablet:

- 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
- Maintenance of healing of erosive esophagitis (EE)

ZEGERID® with Magnesium Hydroxide 40 mg Chewable tablet:

- 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 (test for package insert) and submitted labeling (package insert submitted March 23, 2006; immediate container and carton labels submitted March 24, 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 21-850**." 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 March 23, 2006. These commitments are listed below.

A development study consisting of expanded dissolution testing using the USP Apparatus 1 [(b) (4)] at [(b) (4)]m (with and without surfactant), in addition to your proposed method and specification, for a ---- od of six months after approval according to the following schedule:

Protocol Submission:	Not later than May 1, 2006
Study Start:	Not later than June 15, 2006
Final Report Submission:	Not later than October 31, 2006

This testing would include both new production lots and those lots that are currently on stability as they come due using your proposed method and specification for lot release. The dissolution data should be submitted to the Agency for review as a supplement to NDA 21-850 to establish both a final method and release specification based on the accumulated production experience.

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 the Division of Gastroenterology Products 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}
Joyce Korvick, M.D., M.P.H.
Deputy 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
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