DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-706

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

Dear Dr. Simmons:

Please refer to your new drug application **(**NDA) dated February 25, 2004, received February 26, 2004, submitted pursuant to section 505 (b)(2) of the Federal Food, Drug, and Cosmetic Act for Omeprazole Immediate-Release Powder for Oral Suspension, 40 mg.

We acknowledge receipt of your submissions dated March 30, April 22, June 25, July 6, July 23, July 26, August 13, September 7, September 10, September 20, October 15, October 20, October 25, October 27, October 29, November 22, December 2, and December 15, 2004.

This new drug application provides for the use of Omeprazole Immediate-Release Powder for Oral Suspension, 40 mg for short-term treatment (4-8 weeks) of active benign gastric ulcer, and prevention of upper gastrointestinal bleeding in critically ill patients.

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,) and submitted labeling (package insert submitted December 15, 2004, immediate container and carton labels submitted November 22, 2004). 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 NDA21-706**." Approval of this submission by FDA is not required before the labeling is used.

In addition, you must submit the content of labeling in electronic format as described in 21 CFR 314.50 (1)(5). Current guidance for industry specifies that the content of labeling should be provided in PDF or SPL file format. This new submission requirement was published on December 11, 2003 (68 FR 69009) and was effective June 8, 2004. For additional information, consult the following guidance for industry: *Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004).

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 deferring submission of your pediatric studies for ages 2 to 16 years until December 26, 2008.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

These will be pediatric studies that can be open-label, utilizing an historical control. A PK/PD study to determine the appropriate dose in this population is recommended prior to initiating the clinical outcome study.

Deferred pediatric study under PREA for the treatment or prevention of upper gastrointestinal bleeding in critically ill pediatric patients' ages 2 to 11 years old and 12 to 16 years old.

Protocol submission by:	December 26, 2005 (1 year post-approval)
Study start:	December 26, 2006 (2 years post-approval)
Final Report Submission:	December 26, 2008 (3 years post-approval)

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

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 this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 301-827-7475.

Sincerely,

{See appended electronic signature page}
Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and
Coagulation Drug 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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