DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022456 **NDA APPROVAL**

Santarus, Inc.
Attention: Maria Bedoya-Toro, PhD, MBA
Vice President
Regulatory Affairs and Quality Assurance
3721 Valley Center Drive Suite 400
San Diego, CA 92130

Dear Dr. Bedoya-Toro:

Please refer to your new drug application (NDA) dated January 28, 2009, received February 4, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Omeprazole/Sodium Bicarbonate/Magnesium Hydroxide Tablets, 20 mg/750 mg/343 mg and 40 mg/750 mg/343 mg.

We acknowledge receipt of your submissions dated January 28, 2009, February 9, 2009, February 27, 2009, March 11, 2009, March 13, 2009, May 21, 2009, May 26, 2009, June 3, 2009, June 5, 2009, June 12, 2009, July 29, 2009, July 30, 2009, August 21, 2009, August 26, 2009, August 27, 2009, September 14, 2009, September 28, 2009, October 13, 2009, October 28, 2009, November 2, 2009, November 12, 2009, November 16, 2009, November 23, 2009, November 30, 2009, and December 3, 2009.

This new drug application provides for the use of Omeprazole/Sodium Bicarbonate/Magnesium Hydroxide Tablets for the following indications:

Omeprazole/Sodium Bicarbonate/Magnesium Hydroxide Tablets, 20 mg/750 mg/343 mg:

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

Omeprazole/Sodium Bicarbonate/Magnesium Hydroxide Tablets, 40 mg/750 mg/343 mg:

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

We have 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 and with the minor editorial revision listed below.

The format of the Contraindications Section of the Full Prescribing Information was revised (deletion of bullet points).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "**SPL for approved NDA 022456**."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 3, 2009, submission containing final printed container labels.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

Please refer to the Division of Medication Error and Prevention and Analysis letter dated November 19, 2009. If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

For the indications of short-term treatment of active duodenal ulcer and short-term treatment (4 to 8 weeks) of active benign gastric ulcer, we are waiving the pediatric study requirement because the necessary studies are impossible or highly impracticable.

For the indications of treatment of heartburn and other symptoms associated with GERD, short-term treatment (4 to 8 weeks) of erosive esophagitis which has been diagnosed by endoscopy, and maintenance of healing of erosive esophagitis, we are waiving the pediatric study requirement for ages birth to 1 month because the necessary studies are impossible or highly impracticable; additionally we are waiving the pediatric study requirements for age 1 month to 16 years because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this group.

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 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 final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Todd Phillips, Regulatory Project Manager, at (301) 796-4857.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22456	ORIG-1	SANTARUS INC	ZEGERID

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
12/04/2009