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**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER(S)**

# NDA 21-636

**Trade Name:** Zegerid Powder for Oral Suspension, 20 mg

**Generic Name(s):** (omeprazole)

**Sponsor:** Santarus, Inc.

**Agent:**

**Approval Date:** June 15, 2004

**Indication:** Provides for short-term treatment of active duodenal ulcer; treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD); short-term of erosive esophagitis which has been diagnosed by endoscopy; and maintenance of healing of erosive esophagitis

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## APPLICATION NUMBER:

21-636

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# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPROVAL PACKAGE FOR:

## APPLICATION NUMBER

# NDA 21-636

# Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-636

Santarus, Inc.
Attention: Christine Simmons, Pharm.D.
10590 West Ocean Air Drive, Suite 200
San Diego, CA 92130

Dear Dr. Simmons:

Please refer to your new drug application (NDA) dated August 14, 2003, received August 15, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zegerid (omeprazole) Powder for Oral Suspension, 20 mg.

We acknowledge receipt of your submissions dated December 9, 2003; January 7 and 15, February 9, 13, 19, and 26, March 2, 11, 16, 22, and 30, April 5 9, 15, 19, 20, and 26, May 11, 13, 18, 19, and 28, June 2, 8, and June 14, 2004.

This new drug application provides for the use of omeprazole powder for suspension 20 for short-term treatment (4-8 wks) of active duodenal ulcer; treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD); short-term treatment (4-8 wks) of erosive esophagitis which has been diagnosed by endoscopy; and maintenance of healing of erosive esophagitis.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use of Zegerid (omeprazole) Powder for Oral Suspension, 20 mg, 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 (immediate container and carton labels submitted June 14, 2004). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the products misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003 (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e. package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. 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 deferring submission of your pediatric studies for ages 2 to 16 years until July 15, 2007.

Your deferred pediatric studies for GERD (symptomatic GERD and Erosive Esophagitis) required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1) Single and multiple-dose pharmacokinetics (PK), pharmacodynamics (PD) and safety study in pediatric patients aged 2 to 11 years.

| | |
|---|---|
| Protocol submission by: | December 15, 2004 (6 mos. post-approval) |
| Study start: | July 15, 2005 (1 year post-approval) |
| Final report submission: | July 15, 2007 (3 years post approval) |

2) Single and multiple-dose pharmacokinetics (PK), pharmacodynamics (PD) and safety study in pediatric patients aged 12 to 16 years.

| | |
|---|---|
| Protocol submission by: | December 15, 2004 (6 mos. post-approval) |
| Study start: | July 15, 2005 (1 year post-approval) |
| Final report submission: | July 15, 2007 (3 years post approval) |

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

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

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 Susan Daugherty, Regulatory Project Manager, at (301) 827-7456.

Sincerely,

*{See appended electronic signature page}*

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Labeling

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

/s/
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Joyce Korvick
6/15/04 01:47:29 PM
for Dr. Robert Justice