



NDA 21-850/S-002  
NDA 21-849/S-003

**SUPPLEMENT APPROVAL**

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

Dear Dr. Bedoya-Toro:

Please refer to your supplemental new drug applications dated May 28, 2009, received May 29, 2009, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid with Magnesium Hydroxide (omeprazole/sodium bicarbonate/magnesium hydroxide) Chewable Tablets (21-850) and Zegerid (omeprazole/sodium bicarbonate) Capsules (21-849).

We acknowledge receipt of your submissions dated December 1, 2009, and January 5, 2010. We also acknowledge your July 13, 2009, submission of 21-636 (b)(4) which served to cross-reference NDA 21-636 Zegerid Powder for Oral Suspension. It is noted that the label for 21-849 (Capsules) is shared by both drug products (Capsules and Powder).

These "Prior Approval" supplemental new drug applications provide for the conversion of the package inserts to Physician's Labeling Rule (PLR) format.

**CONTENT OF LABELING**

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "SPL for approved NDA 21-850/S-002 and 21-849/S-003".

**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 inserts 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 inserts, 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  
5600 Fishers Lane, Room 12B05  
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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

*{See appended electronic signature page}*

Ruyi He, M.D.  
Acting Director  
Division of Gastroenterology Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure: Package Inserts

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21850	SUPPL-2	SANTARUS INC	ZEGERID (OMEPRAZOLE)20/40MG CHEWABLE TAB
NDA-21849	SUPPL-3	SANTARUS INC	ZEGERID (OMEPRAZOLE) 20/40 MG CAPSULE
NDA-21636	SUPPL-8	SANTARUS INC	ZEGERID

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

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/s/

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HEATHER G BUCK  
01/20/2010

RUYI HE  
01/20/2010