DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-849/S-002

Santarus, Inc.
Attention: Charles H. Davis, RAC
Senior Director, Regulatory Affairs
10590 West Ocean Air Drive, Suite 200
San Diego, CA 92130-4682

Dear Mr. Davis:

Please refer to your supplemental new drug application dated August 9, 2007, received August 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zegerid® (omeprazole/sodium bicarbonate) Capsules.

We acknowledge receipt of your submission dated December 13, 2007. Your submission on December 13, 2007 constituted a complete response to our December 6, 2007 action letter.

This "Prior Approval" supplemental new drug application provides for replacing the inactive ingredient magnesium stearate with sodium stearyl fumarate.

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 enclosed agreed-upon labeling text.

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/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide) and/or submitted labeling (package insert submitted August 9, 2007**,** patient package insert submitted August 9, 2007, Medication Guide submitted August 9, 2007). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-849/S-002."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and/or submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually

mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-849/S-002**." Approval of this submission by FDA is not required before the labeling is used.

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

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 Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure: Content of Labeling
Draft Carton & Immediate Container Labels

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

/s/

Eric Duffy

12/21/2007 01:42:23 PM