CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

203634Orig1s000

Trade Name: Uceris 9 mg tablets

Generic Name: budesonide

Sponsor: Santarus, Inc.

Approval Date: February 26, 2013

Indications: provides for the use of Uceris (budesonide) 9 mg tablets indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis

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APPLICATION NUMBER:

203634Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203634

NDA APPROVAL

Santarus, Inc.
Attention: Maria Bedoya-Toro, Ph.D., M.B.A.
Vice President, Regulatory Affairs and Quality Assurance
3721 Valley Centre Drive, Ste. 400
San Diego, CA 92130

Dear Dr. Bedoya-Toro:

Please refer to your New Drug Application (NDA) dated December 14, 2012, received December 16, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Uceris (budesonide) 9 mg tablets.

We acknowledge receipt of your amendments dated January 20, 2012, January 27, 2012, February 10, 2012, February 10, 2012, February 20, 2012, February 24, 2012, February 24, 2012, February 29, 2012, March 06, 2012, March 09, 2012, March 21, 2012, March 26, 2012, March 26, 2012, March 28, 2012, March 29, 2012, March 30, 2012, April 10, 2012, April 25, 2012, April 25, 2012, May 03, 2012, May 09, 2012, May 16, 2012, May 30, 2012, June 01, 2012, June 14, 2012, June 27, June 27, 2012, June 29, 2012, July 20, 2012, July 20, 2012, August 03, 2012, August 03, 2012, August 09, 2012, August 10, 2012, August 17, 2012, September 12, 2012, October 09, 2012, October 19, 2012, October 25, 2012, November 16, 2012, November 30, 2012, December 12, 2012, December 19, 2012, December 21, 2012, December 21, 2012, January 07, 2012, and January 14, 2013.

This new drug application provides for the use of Uceris (budesonide) 9 mg tablets indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

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 revisions listed below:

- On the container (bottle) label, re-locate the "Swallow tablet whole, do not chew or break." statement on the principal display panel (PDP) after the strength statement (so that the net quantity and Rx only statements appear last).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and text for the patient package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and immediate-container labels that are identical to the enclosed carton and immediate-container labels, except with the revisions listed above, 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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with six of the copies individually mounted on heavyweight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 203634**." Approval of this submission by FDA is not required before the labeling is used.

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

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Kevin Bugin
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5143
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

ADVISORY COMMITTEE

Your application for Uceris was not referred to an FDA advisory committee because this drug is not the first in its class.

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 indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 5 years because necessary studies are impossible or highly impracticable. This is because there is a low incidence of the disease in this age group.

We are deferring submission of your pediatric study for ages 5 to 17 years for this application because this product is ready for approval for use in adults and the pediatric study have not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1997-1 An 8-week randomized, double blind, placebo-controlled trial in children 5 to 17 years of age with active, mild to moderate ulcerative colitis. The trial will evaluate pharmacokinetics (PK), efficacy for induction of remission, and safety of at least 2 doses of Uceris (budesonide). The effects of 8 weeks of Uceris (budesonide) on the HPA axis will be assessed.

Final Protocol Submission:	09/2013
Trial Completion:	06/2016
Final Report Submission	09/2016

Submit the protocol(s) to your IND 074882 with a cross-reference letter to this NDA.

Reports of this/these required pediatric postmarketing study(ies) must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Kevin Bugin, Regulatory Project Manager, at (301) 796-2302.

Sincerely,

{See appended electronic signature page}

Andrew E. Mulberg, MD, FAAP, CPI
Deputy Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

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

/s/

ANDREW E MULBERG
01/14/2013