DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

February 1, 2013

Maria Bedoya- Toro, Ph.D.
Santarus, Inc.
3611 Valley Centre Drive, Suite 400
San Diego, CA 92130

Dear Ms. Bedoya- Toro:

Your petition to the Food and Drug Administration requesting (1) to develop and publish an individual bioequivalence recommendation for budesonide extended release tablets and (2) to refrain from approving any abbreviated new drug application that identifies Uceris™ (budesonide) extended release tablets as the reference listed drug unless the generic product is shown to be bioequivalent based on appropriate data from a clinical efficacy endpoint study, was received by this office on 2/1/2013. It was assigned docket number FDA-2013-P-0127/CP1, and it was filed on 2/1/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)