DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 24 2013

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

Re: Docket No. FDA-2013-P-0127

Dear Dr. Bedoya-Toro:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 1, 2013. Your petition requests that the Agency (1) develop and publish an individual bioequivalence recommendation for budesonide extended release tablets and (2) refrain from approving any abbreviated new drug application citing Uceris™ (budesonide) extended release tablets as the reference listed drug unless the generic product meets certain criteria.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research