DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 19, 2019

Marcia Kayath
Head, US Clinical Development and
Medical Affairs
Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, NJ 07935

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner to take the following actions 1) Require ANDAs that reference ENTRESTO® to demonstrate API sameness based on the chemical structure of the sacubitril and valsartan active ingredients present in the finished dosage form 2) Revise FDA's draft guidance document regarding sacubitril/valsartan oral tablets was received by this office on 04/18/2019.

It was assigned docket number FDA-2019-P-1893. 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,

Karen Malvin Digitally signed by Karen Malvin
Date: 2019.04.19 12:41:37 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
OC/OO/OEMS/DIG