FDA U.S. FOOD & DRUG ADMINISTRATION

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

Re: Docket No. FDA-2019-P-1893

OCT 15 2019

Dear Dr. Kayath:

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 April 18, 2019, and submitted on behalf of Novartis Pharmaceutical Corporation. Your petition requests that the Agency require Abbreviated New Drug Applications referencing Entresto (sacubitril/valsartan) tablets, 24/26 milligrams (mg); 49/51 mg; 97/103 mg, "to demonstrate API sameness based on the chemical structure of the sacubitril and valsartan active ingredients present in the finished dosage form." Your petition also requests that the Agency make certain revisions to its Draft Guidance on sacubitril/valsartan relating to "API sameness" and bioequivalence recommendations.

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 J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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