David Platt, MD
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936

March 28, 2023

Re: Docket No. FDA-2022-P-2228

Dear Dr. Platt:

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 September 12, 2022, and submitted on behalf of Novartis Pharmaceuticals Corporation. Your petition requests that the Agency take the following actions:

1. Refrain from approving any [abbreviated new drug application (ANDA)] referencing NDA 207620 during the 3-year exclusivity period covering the labeling changes approved in the February 2021 supplement, including any ANDA that seeks to add language to, or otherwise revise, the existing indication statement in order to omit the exclusivity-protected use.

2. Refrain from approving any ANDA referencing NDA 207620 until the expiration of [U.S. Patent Nos. 9,517,226; 9,937,143; and 11,135,192 (collectively, the heart failure with preserved ejection fraction (HFpEF) Patents)] if that ANDA contains a section viii statement to those patents and seeks to omit the patent-protected use in HFpEF patients.

3. Refrain from approving any ANDA referencing NDA 207620 until the expiration of [U.S. Patent No. 11,058,667 (the '667 Patent)] if that ANDA contains a section viii statement and seeks to omit the modified dosing regimen for [heart failure with reduced ejection fraction (HFrEF)] patients not taking an ACE inhibitor or ARB, or who were previously taking low doses of these agents.[1]

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 -S

Digitally signed by Carol Bennett -S
Date: 2023.03.28 13:36:49 -04'00'

Carol J. Bennett

[1] Petition at 4.

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