September 13, 2022

David Platt
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Sent via email to: stephanie.agu@hoganlovells.com

Dear Petitioner:

Your submission requesting that the Commissioner:

1. Refrain from approving any 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. Approving an ANDA during the exclusivity period exceeds FDA's statutory and regulatory authority with regard to ANDA "same labeling" standards and would represent an impermissible departure from longstanding agency precedent and interpretations.

2. Refrain from approving any ANDA referencing NDA 207620 until the expiration of the HFpEF Patents if that ANDA contains a section viii statement to these patents and seeks to omit the patent-protected use in HFpEF patients. As with the 3-year exclusivity described above, FDA cannot draft an indication statement for a proposed ANDA product by deleting the use protected by the HFpEF Patents from the current ENTRESTO indication statement.

3. Refrain from approving any ANDA referencing NDA 207620 until the expiration of the '667 Patent if that ANDA contains a section viii statement and seeks to omit the modified dosing regimen for HFrEF patients not taking an ACE inhibitor or ARB, or who were previously taking low doses of these agents. Omission of this patent-protected dosing regimen would lead to an increase in clinically significant adverse events for such patients under the higher starting dose and quicker up-titration schedule described in the standard dosing regimen. Moreover, an increase in adverse events could result in diminished effectiveness if these patients are unable to tolerate the standard starting dose and titration schedule. For these reasons, an ANDA product that omits this information would be less safe and effective than ENTRESTO for the remaining conditions of use that are not protected by the '667 Patent.

Your application was received and processed under CFR 10.30 by this office on 09/12/2022 and it was assigned docket number FDA-2022-P-2228. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S

Digitally signed by Karen P. Malvin -S
Date: 2022.09.13 13:53:50 -04'00'

Karen Malvin
Acting Director
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cc:

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