



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 5, 2020

Rose Zhao
Emprise Pharma, LLC
132 Charlestown Hunt Dr.
Phoenixville, PA 19460

Sent via email to: zhaor@emprisepharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to allow us to submit an Abbreviated New Drug Application for our new Carvedilol bilayered extended release tablets using Coreg CR capsules as Reference Listed Drug was received by this office on 11/02/2020.

It was assigned docket number FDA-2020-P-2166. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)