File No. BIO/CT/21/000139
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110002
Date:

To,
M/s Glaxosmithkline Pharmaceuticals Limited,
252, Dr. Annie Besant Road, Worli,
Mumbai-400030, Maharashtra, India.

Subject: Submission for approval of PMS(active surveillance study) with protocol number 217046 amendment dated 03.01.2022 titled "**An observational, 24 week, open-label, multi-center, prospective post marketing surveillance study to evaluate the safety, tolerability and patient treatment experience (PTE) of mepolizumab administration via autoinjector for adult patients aged 18 years or older suffering with severe eosinophilic asthma**"-regarding

Ref.: 1) Your online application BIO/CT04/FF/2021/28329 dated 29.09.2021 2) MOM of 56th SEC(pulmonary) held on 07.12. 2021.

Sir,

With reference to the subject cited above, your application has been reviewed based on the submitted documents and further deliberated in the 56th SEC (Pulmonary) meeting held on 07.12.2021. As recommended by the SEC, this Directorate has no objection for the conduct of subject PMS(active surveillance study) vide Protocol 217046 amendment dated 03.01.2022 for the drug viz **Mepolizumab Powder for Solution for Injection 100 mg/mL in a prefilled syringe in either a safety syringe or an autoinjector (pen) device** under the provisions of Fifth Schedule of New Drugs and Clinical Trial Rules, 2019 subject to the following condition:

1.The firm has to submit the ICF and CRF before initiation of the study.
2. The firm should submit the date of commencement of the subject study and duly signed complete report of active surveillance study as per the approved protocol from the investigator along with conclusion of the study in due course of time.

Yours faithfully,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073a55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6d2f465c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.02.07 17:07:33 +05'30'

(Dr. V.G. Somani)
Drugs Controller General (India)