Zenlabs Ethica Ltd.

CIN NO. : L74900CH1993PLC033112, GSTIN NO. : 03AAFCS6226G1ZL

Regd. Office : Plot No. 194-195, 3rd Floor, Industrial Area, Phase-II, Chandigarh -160 002
Tel. : 0172-465 1105, Fax : 0172-265 6855
E-mail: queries@zenlabsethica.com, Website : www.zenlabsethica.com

Date: 02.09.2022

To,
General Manager
Corporate Relationship Department
BSE LIMITED
Phiroze Jeejeebhoy Towers
Dalal Street, Mumbai-400001
Maharashtra

SUB: Corporate Announcement

Ref: Zenlabs Ethica Limited Scrip Code: 530697

Dear Sir /Madam,

Pursuant to Regulation 30 of SEBI (Listing Obligation and Disclosure Requirements) Regulation, 2015, we wish to inform you that:

- The Group Company / the manufacturing arm of **ZENLABS ETHICA LTD i.e., M/s PREET REMEDIES LTD** has got approved its Drug Distribution Licence by FDA Ghana, Cantonments Accra in Ghana vide Application No. **AFH0458/21** bearing Reference number **-FDA/HPT/DHM/DNC/FHR/22/0883** on 29.06.2022.

- The registration is valid for 3 years and expires on 1st July, 2025 as Approved by FDA Ghana, Cantonments Accra in Ghana.

You are requested to kindly take the same on record.

Thanking You,

Yours Truly,

FOR ZENLABS ETHICA LIMITED

ZENLABS ETHICA LIMITED CHANDIGARH

TANVI CHHABRA
COMPANY SECRETARY

cc: Supporting Document in annexure below

Head Office
Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana
(+233)-302-233200/235100
(+233)-551-112223/4/5 (Hotline)
Email: fda@fda.gov.gh
Digital Address: GA-237-7316

FDA/HPT/DHM/DNC/FHR/22/0883

29th June 2022

The Superintendent Pharmacist
Boras Bee Pharmaceuticals Limited
P.O. Box SK 1783
Sakumono Tema
Ghana

Dear Sir,

DRUG REGISTRATION FOR APPLICATION NUMBER: AFH0458/21

This is to inform you that the Food and Drugs Authority (FDA) has completed the review of your application submitted for the registration of **SILDMED 100 TABLETS** (Each film coated tablet contains Sildenafil 100mg) pursuant to Section 118 of the Public Health Act of 2012 (Act 851).

Please quote this application number in all future correspondence with the FDA concerning this application.

The speciality drug has been issued with the registration number; **FDA/SD.223-061078**

The registration is valid for three (3) years and expires on **July 1, 2025.**

Please note that it is your responsibility to apply for variation of the registration (as per the FDA's variation guidelines) and also renewal of the registration in due time (not later than three months prior to the expiry date of the registration).

A certificate of registration will be issued upon submission of the following;

1. Revise the FPP release and shelf-life specification to include impurity D since this impurity has been identified as degradant.

2. Submit signed copy of the revised specification.

The conditions which apply to this registration are as follows:

- The speciality drug shall be dispensed as a **Prescription-Only Medicine (POM).**

- The speciality drug must conform to all the details submitted in your application and as modified in subsequent correspondence.

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- The finished pharmaceutical product cannot be advertised through the electronic and print media. They can only be advertised via product launch/promotional material after the advertisement has been vetted and approved by the FDA.

- No changes may be made to the quality specifications, composition, packaging materials, manufacturing process and site of manufacture of the speciality drug without prior approval from the FDA.

- Importation of the finished pharmaceutical product is not permitted after the period of validity of the registration has expired.

You are to monitor the quality of the finished pharmaceutical product on the market and report any quality defects to the FDA for the appropriate regulatory action to be taken.

You are requested to monitor the safety of the product granted marketing approval and report all adverse reactions or events to the FDA as per Section 125, Subsection 2 of the Public Health Act, 2012, Act 851.

Additionally, you are to ensure that you promptly communicate any change in the safety information on the finished pharmaceutical product to the FDA.

Yours faithfully,

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER

cc: The Head of Regulatory Affairs, Preet Remedies Limited, 183-186 HPSIDC Industrial Area, Baddi 173205, H.P., India.

DCEO, Health Products and Technologies Division, FDA.

DCEO, Technical Operations Division, FDA.

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