

File No. FDC/MA/21/000156
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-23236965
Fax No. :011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

08 OCT 2021

To,

M/s. Zydus Healthcare Ltd.,
Zydus Corporate Park,
Scheme No. 63, Survey No. 536,
Khoraj (Gandhinagar), Nr, Vaishnodevi Circle,
S.G. Highway, Ahmedabad-382481, Gujarat, India.

Subject: Permission to conduct Phase III clinical trial with the FDC of Vilanterol Trifenatate eq. to Vilanterol + Fluticasone Furoate (12.5mcg + 50mcg & 12.5mcg + 100mcg) per actuation delivers metered dose inhalation (Vide protocol no. 21-06, version no. 00, dated: 08.07.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 15.07.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-139/2021** under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,



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

CONDITIONS OF PERMISSION

- I. Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;
- II. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:
 - i. Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be;
 - ii. Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;
- III. In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- IV. The Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUGPermission no.: CT-06-139/2021

1. The Central Licencing Authority hereby permits **M/s. Zydus Healthcare Ltd., Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr, Vaishnodevi Circle, S.G. Highway, Ahmedabad-382481, Gujarat, India.** (Name and full address with contact details of the applicant) to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. 21-06, version no. 00, dated: 08.07.2021**) in the below mentioned clinical trial sites.
2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date: 08 OCT 2021V-h
Central Licencing Authorityडॉ. **Stamp**आयुषी नमोः (एन.एन.ए.)
स्वास्थ्य एवं परिवार कल्याण विभागएन.डी.ए. भवन, बोटला रोड, आई.टी.ओ
नई दिल्ली-110002

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Vilanterol Trifenatate eq. to Vilanterol + Fluticasone Furoate (12.5mcg + 50mcg & 12.5mcg + 100mcg) per actuation delivers metered dose inhalation
Therapeutic class:	Long-acting beta ₂ -adrenergic agonist (LABA) and inhaled corticosteroid (ICS)
Dosage form:	Metered Dose Inhalation
Composition:	Vilanterol Trifenatate eq. to Vilanterol + Fluticasone Furoate (12.5mcg + 50mcg & 12.5mcg + 100mcg) per actuation delivers metered dose inhalation
Indications:	Indicated in the patients with persistent asthma aged 18 years and older.

Details of clinical trial site:

Names and address of clinical trial site:	As per annexure- A
Ethics committee details:	As per annexure- A
Name of principal investigator:	As per annexure- A

Permission no.: CT-06-139/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Jaydip Deb	Professor & Head, Department of Respiratory Medicine, Nil Ratan Sircar (N.R.S.) Medical College & Hospital, 138, AJC Bose Road, Kolkata – 700014, West Bengal	Institutional Ethics Committee, NRS Medical College and Hospital, 138, AJC Bose Road, Kolkata – 700014, West Bengal Registered (ECR/609/Inst/ WB/2014/RR20)
2	Dr. Raghumanda Sunil Kumar	Professor & Head, Department of Pulmonology, Government Medical College and Government General Hospital, Srikakulam-532001, Andhra Pradesh	Institutional Ethics Committee, Government Medical College and Government General Hospital, Srikakulam – 532001, Andhra Pradesh Registered (ECR/492/Inst/A P/2013/RR-20)
3	Dr. Neeraj Gupta	Professor & Head, Department of Pulmonary Medicine, Jawahar Lal Nehru Medical College & Attached Hospitals, Kala Bagh, Ajmer – 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer – 305001, Rajasthan Registered (ECR/1156/Inst/ RJ/2018)
4	Dr. Manish Kumar Jain	Consultant Pulmonologist, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector No. 7, Vidhyadhar Nagar, Jaipur - 302039, Rajasthan	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector No. 7, Vidhyadhar Nagar, Jaipur - 302039, Rajasthan Registered (ECR/1222/Inst/ RJ/2019)
5	Dr. Rajkumar Gautam Nikalje	Consultant Pulmonologist, Lifepoint Multispecialty Hospital, 145/1, Mumbai-Bangalore Highway, Near Hotel Sayaji, Bhumkar Chowk, Wakad, Pune - 411057, Maharashtra	Lifepoint Research Ethics Committee, Life Point Mutispecialty Hospital, 145/1, Mumbai-Bangalore highway Near Hotel Sayaji, Wakad, Pune - 411057, Maharashtra Registered (ECR/751/Inst/M H/2015/RR-21)
6	Dr. Gautam S.	Consultant Pulmonologist, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi (Belgaum) – 590002, Karnataka	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi – 590002, Karnataka Registered (ECR/1242/Inst/ KA/2019)
7	Dr. Shreehas Suhas Bardapurkar	Consultant Pulmonologist, Ishwar Institute of Health Care, Ishwar Heights, Plot No. 7, Gut No. 6/1, Beside Punjabi Bhavan, Mumbai-Nashik Highway, Padegaon, Aurangabad - 431002, Maharashtra	Institutional Ethics Committee, Ishwar Institute of Health Care, Ishwar Heights, Plot No. 7, Gut No. 6/1, Beside Punjabi Bhavan, Padegaon, Aurangabad - 431002, Maharashtra Registered (ECR/988/Inst/M H/2017/RR-20)

Place: New Delhi

Date:

08 OCT 2021

Central Licencing Authority

डा. वी. सी. सोमानी
 औषधि महानियंत्रक (भारत)
 स्वास्थ्य सेवा महानिदेशालय
 स्वास्थ्य एवं परिवार कल्याण मंत्रालय
 क.डी.ए. भवन, कोटला रोड, आई.टी.आ
 नई दिल्ली-110002