Diary No: 6943
Date: 26.02.2018

F. No.12-16/16-DC (Pt-B)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi – 110002 (India)
New Drugs Division

Tele No.011-23236065
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Dated. 13-08-2018

To
M/s. A. Menarini India Private Limited,
2102, Tower 3, Indiabulls Finance Center,
Senapati Bapat Marg, Elphinstone Road (W),
Mumbai 400013, India

Subject: Permission for conducting clinical study entitled, "A Double-blind, Double-dummy, Randomized, Parallel-group, Active Controlled, Multi-centre, Phase III Study to Compare the Efficacy and Safety of Bilastine 20 mg Once Daily and Desloratadine 5 mg Once Daily for the Treatment of Allergic Rhinoconjunctivitis (Seasonal)" - regarding.

CT NOC No. CT/ND/35/2018

Reference: Your application no Menarini/SAR/18/01 dated 26.02.2018 on the subject mentioned above.

Sir,
This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigator and as per the **Protocol No: MAIN/17/Bil-SAR/001, Version No:1.0, Dated 22.01.2018** submitted to this Directorate.

S.No.	Investigator and Trial site	Ethics Committee Name and Registration Number
1.	**Dr. Jaimanti Bakshi** Dept. of Otolaryngology, Postgraduate Institute of Medical Education and Research Nehru Hospital, 5th Floor, Sec-12 Chandigarh-160012, India	Institutional Etics Committee, Room No. 6006, IEC Office, A, 6th Floor, PN Chuttani Block, PGIMER, Sector 12, Chandigarh- 160012 **ECR/25/Inst/CH/2013/RR-16**
2.	**Dr. RAS Kushwaha** King George Medical, University I Shahmina Road, Chowk Lucknow-226003, UP, India	Institutional Etics Committee Office of research Cell, Administrative Block King Georges Medical University Lucknow-226003, UP, India **ECR/262/Inst/UP/2013/RR-16**
3.	**Dr. Vipin Ekhar** Indira Gandhi Medical College and Hospital, CA Road Nagpur-440018 Maharashtra, India	Ethics Committee Indira Gandhi Medical College, Dept. of Pharmacaology, Central Avenue Road, Near Main Railway Station, Nagpur-440018 Maharashtra, India railway Station **ECR/485/Inst/MH/2013/RR-16**
4.	**Dr. Rajesh Vishwakarma** Civil Hospital F5, Civil Hospital Campus Asarwa, Ahmadabad-380016 Gujarat India	GCRI/GCS Ethics committee The Gujarat Cancer and research Institute, Civil Hospital Campus, Asaarwa, Ahmedabad-380016, Gujarat, India **ECR/41/Inst/GJ/2013/RR-16**

S.No	Investigator and Trial site	Ethics Committee Name and Registration Number
5.	**Dr. V. Viswanadh Gandhi Manchu,** King George Hospital, Dept. of Medicine, New Block Research Room no.2, King George Hospital, Visakhapatnam- 530002 Andhra Pradesh	Institutional Ethics Committee, M/s King George Hospital, Visakhapatnam- 530002 Andhra Pradesh **ECR/197/Inst/KGH/2013**
6.	**Dr. Sudhir Kumar** Indira Gandhi Institute of Medical Sciences, Sheikhpura Patna-800014 Bihar, India	Institutional Ethics Committee Indira Gandhi Institute of medical sciences, Sheikhpura Patna-800014 Bihar, **ECR/640/Inst/BR/2014**
7.	**Dr. Satish Kumar K.N** KR Hospital Mysore Medical college and research Institute, Irwin Road Mysore-570021, India	Institutional Ethics Committee, Mysore Medical college& Research Institute and associated Hospital, Department of Pathology, K.R Hospital ,Irwin Road Mysore-570021, India **ECR/134/Inst/KA/2013/RR-16**
8.	**Dr. Telang Rahul** Sasoon Hospital (BJ medical college), Jai prakash Narayan Road, Near Pune railways station, Pune-Maharashtra India -411001	Institutional Ethics Committee of BJ medical college and Sasson general hospital, Dept of Pharmacology, BJ Govt Medical College Sasoon Road, Pune-411001 **ECR/280/Inst/Maha/2013/RR-16**
9.	**Dr. Prasanna Kumar T** M.S Ramaiah Medical college and hospital, M S Ramaiah Nagar , MSRIT Post Bangalore-560054, Karnataka, India	Ethics Committee, M.S Ramaiah Medical College and Hospital, M S Ramaiah Nagar, MSRIT Post , Bangalore- 560054, Karnataka, India **ECR/215/Inst/KA/2013/RR-16**
10.	**Dr. R Balaji** Dept. of Community medicine, SRM Medical college hospital and research Centre, SRTI University Potheri, Kanchipuram-603203, Tamil Nadu, India	Institutional Ethics committee, SRM medical college hospital and research Centre, SRTI University Potheri Kanchipuram-603203,Tamil Nadu, India **ECR/431/Inst/TN/2013/RR-16**
11.	**Dr. Vishak Acharya K** Department of Pulmonary medicine, Kasturba Medical college and hospital, Ambedkar Circle, Mangalore, Karnataka India -575001	Institutional Ethics committee HR Department, Kasturba Hospital, Manipal-576104, India **ECR/146/Inst/KA/2013/RR-16**
12.	**Dr. Abhishek Karmalkar** P.D.E.A's Ayurveda rugnalaya and Stering Multi specialty Hospital, Sec No-27, Near Bhel Chowk Nigdi Pradhikaran, Pune-411044, Maharashtra, India	Ethics committee, Stering Hospital, Sec No-27, Near Bhel Chowk Nigdi Pradhikaran Pune 411044 Maharashtra, India **ECR/542/Inst/MH/2014/RR-16**

S.No	Investigator and Trial site	Ethics Committee Name and Registration Number
13.	**Dr. Ashish Nikhare** Lata Mangeshkar Hospital, 5 YMCA complex, Maharaj bagh Road, Sitabuldi, Nagpur -440019 Maharashtra India	Institutional Ethics committee NKP Salve Institute of Medical Sciences and Lata Mangeshkar Hospital Digoh Hills, Hingna Road, Nagpur- 400019 Maharashtra India **ECR/88/Inst/MH/2013/RR-16**
14.	**Dr. Inderneel Basu** Popular Hospital, N10/60, DLW Road Varanasi- 221004 UP	Popular Hospital Ethics Committee N10/60, DLW Road Kakarmatta Varanasi- 221004 UP **ECR/721/Inst/UP/2015**
15.	**Dr. Shweta Gogia** Sir Ganga Ram Hospital Pusa Road, New Road, New Delhi-110060 India,	Sir Ganga Ram Hospital Ethics committee, Room no 1496, IV Floor Old Building Rajinder Nagar, New delhi-110060, India **ECR/20/Inst/DL/2013/RR-2016**
16.	**Dr. Sandeep Kumar Gupta** MV Hospital and Research center 314/30 Mirza Mandi Chowk Lucknow 226003, Uttar Pradesh, India	Institutional Ethics committee MV Hospital and Research center, 314/30 Mirza Mandi Chowk Lucknow 226003, Uttar Pradesh, India **ECR/13/Inst/UP/2013/RR-16**
17.	**Dr. Rupjyoti Das** GNRC Hospital GNRC complex Dispur Guwahati-781006, Assam, India	Ethics committee Institute of Neurological Sciences, GNRC Hospital Complex, near Supermarket, Guwahati-781006, Assam, India **ECR/778/Inst/AS/2015**
18.	**Dr. Tapan Rohitabhai shah** SanginiHopsital 1st floor , Santori Square, B/H Abhishree Complex, Opp star bazaar, near jodhpur cross road, satellite Ahmedabad-380015,Gujrat India	Sangini hospital Ethics committee, Sangini Hospital 1st floor ,Santori Square, B/H Abhishree Complex, Opp. star bazaar, near jodhpur cross road, satellite Ahmedabad-380015, Gujrat India **ECR/147/Inst/GJ/2013/RR-16**
19.	**Dr. Vijay Shukla** Ajanta research centre Ajanta hospital and IVFC centre,765, ABC complex, Kanpur Road, Alambagh Lucknow 226005, Uttar Pradesh, India	Institutional Ethics committee, Ajanta research centre Ajanta hospital and IVFC Centre,765, ABC complex, Kanpur Road, Alambagh Lucknow 226005, Uttar Pradesh, India **ECR/611/Inst/UP/2014/RR-17**
20.	**Dr. Aman Khana** Aman Hospital and Research Centre 15, Shashwat ,Opp.ESI Hospital Gotri Road, Vadodra 390021,Gujarat India	Institutional Ethics committee, Aman Hospital and Research Centre 15, Shashwat ,Opp.ESI Hospital Gotri Road, Vadodra 390021,Gujarat India **ECR/857/inst/GJ/2016**
21.	**Dr. Vineet Shukla** KRM Hospital and research Centre 3/92-93, VijantKhand, Gomati Nagar, Lucknow- UP - India 226010	Ethics Committee, KRM Hospital, 3/92-93,Vijantkhand, Gomti Nagar, Lucknow-226010, UP, India **ECR/848/inst/UP/2016**

Kindly note that the clinical trial permission is subject to the following conditions:-

a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.

b) Approval of Institutional Ethics Committee duly registered with CDSCO (under Rule 122DD of Drugs & Cosmetics Rules) should be obtained and submitted to this Directorate before initiation of the study.

c) Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.

d) Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority.

e) Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.

f) In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.

g) The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.

h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i) Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

j) The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc.

k) The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

l) In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015.

m) The bulk drug to be used in manufacturing of finished formulation intended to be used in the clinical trial and clinical trial batches of finished formulation shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.

n) If the clinical trial batches are different from that of the primary batches for which data have been submitted, stability reports for clinical trial batches are to be submitted as per Appendix IX of schedule Y of drugs and Cosmetics Rules for Drug substances and formulation along with Clinical study Report.

o) Informed consent Documents (ICD) viz. Patient information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect as per requirments specified in Appendix V of Schedule Y of the Drugs and Cosmetics Rules,1945 must be approved from respective Ethics Committee and Submitted to CDSCO before enrolling first subject at the respective site.

p) It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)