Diary No: 2819
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F. No. 12-74/14-DC-(Pt-A)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road
New Delhi – 110002 (India)
Dated: 05-03-2019

To
M/s. Hetero Labs Ltd,
Hetero Corporate, Industrial Estates,
H. NO.7-2-A2, Santhanagar, Hyderabad-500018,
Telangana State, India.

Subject: **"A Phase III, Multi-Center, Comparative, Randomized, Parallel Group Study to Evaluate the Efficacy and Safety of Cetilistat in Adult Obese Patients"- regarding.**

Reference: Application No.-HLL/DCGI/NDA/17-040 dated 21/08/2017 on the subject mentioned above.

CT NOC No. : CT/ND/21/2019

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 investigators and as per the **Protocol No: HCR/III/CETIOBE/10/2015, Version 2.0, dated 02/November/2018** submitted to this Directorate.

S. No	Name and Designation	Address of Site And Type of Hospital , No of bed	Name of Ethics Committee and address with Ethics Committee registration No
01	Dr. BalRam Sharma Associate Professor MBBS,MD(General Medicine) D.M.(Endocrinology)	Department of Endocrinology, Room No- 42, Fourth Floor, Dhanvantri OPD Block SMS Hospital Jaipur-302004	Office of Ethics Committee SMS Medical College & Attached Hospitals, Jaipur, First Floor ,Dhanvantri OPD Block SMS Hospital ,JLN Marg Jaipur-302004,Rajasthan,

			India **ECR/26/Inst/RJ/2013/RR-16**
02	Dr. Pranab Kumar Sahana Associate Professor MBBS. MD (Gen. Medicine) DM(Endocrinology)	NRS MEDICAL College & Hospital, 138 AJC Bose Road, Kolkata-700014, West Bengal. India	Ethics Committee NRS Medical College,138,AJC Bose Road,Kolkata-700014 **ECR/609/Inst/WB/2014-RR-17**
03	Dr. B. Thrilok Chander Associate Professor MBBS, DCH, MD(General Medicine)	In Patient Block, 2nd Floor Department of Medicine, Gandhi Hospital, Musheerabad, Secunderabad, Telangana 500003	Institutional Ethics Committee ,Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabad,Telangana 500003 **ECR/180/Inst/AP/2013/RR-16**
04	Dr. B. Srinivasa Rao, Associate Professor MBBS,MD(General Medicine)	Department of Gen. Medicine, Rajiv Gandhi Institute of Medical Sciences & RIMS Govt. General Hospital, Srikakulam-532001,Andhra Pradesh, India	Institutional Ethics Committee Rajiv Gandhi Institute of Medical Sciences & RIMS Govt. General Hospital,Srikakulam-532001,Andhra Pradesh, India **ECR/492/Inst/AP/2013/RR-16**
05	Dr. Hemant Ramsharan Gupta MBBS, MD (Internal Medicine)	Grant Govt. Medical College & Sir JJ Hospital, Department of Medicine, Main Building, Byculla, Mumbai- 400008,Maharashtr	Institutional Ethics Committee Department of Pharmacology, Sir JJ Hospital, Mumbai-400008 **ECR/382/MH/INST/RR-**

		a India.	2016
06	Dr. Deo Nidhi Mishra Director & Chief Consultant Physician MBBS,MD(Medicine)	Nirmal Hospital Opp.MLB Medical College, Gate No.3 Jhansi (U.P)-284128	Institutional Ethics Committee, Nirmal Hospital Institutional Ethics Committee, Nirmal Hospital Campus, Opp. MLB Medical College gate no.3 Kanpur Road jhansi-284128(U.P) **ECR/325/Inst/UP/2013/RR-16**
07	Dr. Kancharla Sudhakar Professor & HOD MBBS, MD(General Medicine)	New Govt. General Hospital, (Associated By Govt. Siddhartha Medical College)Govt. Siddhartha Medical College Campus, Gunadala, Vijaya wada-520008,Andhra Pradesh, India	Institutional Ethics Committee Siddhartha Medical College & Govt. General Hospital (IEC SMC & GGH) Govt. Siddhartha Medical College Campus,Gunadala,Vijayawada520008,Andhra Pradesh, India **ECR/633/Inst/AP/2014/RR-17**
08	Dr. Aman Khanna Director MBBS,MD (Medicine)	Aman Hospital and Research Center 15/Shashwat Opp. E.S.I. Hospital Gotri Road, Vadodara, Gujarat, India-392001	Institutional Ethics Committee Aman Hospital and Research Center 15/Shashwat Opp. E.S.I. Hospital Gotri Road, Vadodara, Gujarat, India-392001 **ECR/857/Inst/GJ/2016**
09	Dr. Kartikeya Parmar Assistant Professor MBBS,MD (Medicine)	Civil Hospital, Asarwa, Ahmedabad,380016, Gujarat,India	Institutional Ethics Committee, B.J. Medical College, and Civil Hospital. Office of Medical Superintendent, Ahmedabad **ECR/72/Inst/2013/RR-2016**
10	Dr. SK. Noushad Ali	ACSR Government	Institutional Ethics

	Assistant Professor MBBS,MD (General Medicine)	Medical College & Hospital, Dargamitta, Nellore-524004	Committee, ACSR Hospital,Dargamitta,Nellore-524004 **ECR/961/Inst/AP/2017**

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 by 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 formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.

n) It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not conveyor 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.

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

p) **Clinical trial protocol should be revised in accordance as SEC committee recommendation as follows:**

1. **The patients with obesity only (BMI more than 30 with or without co-morbidities should be included.**
2. **Patients of diabetes receiving anti-diabetic drugs with potential of reducing body weight should be excluded.**
3. **In case of women of child bearing potential, the women using barrier contraception should only be included.**

Accordingly, revised protocol should be submitted to CDSCO before initiation of the study.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
& Licensing Authority