F. No. BIO/CT/18/000035
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi – 110002

To,

M/s Cadila Healthcare Limited,
Plot Survey No. 23, 25/P, 37, 40/P, 42, To 47,
Sarkhej-Bavla N.H. No-8A,
Opposite Ramdev Masala, Village Changodar,
Tal. Sanand, Ahmedabad, Gujarat (India) – 382213

Subject: Permission for conducting a Phase 1 clinical trial titled "A randomized, double-blind, balanced, two-treatment, two-period, crossover, single dose pharmacokinetic and pharmacodynamic bioequivalence study of Zydus Pegfilgrastim (ZRC-3128) and 'NEULASTA®' (Pegfilgrastim) in healthy adult human subjects under fasting conditions".

Reference: Your Application No. BIO/Form44/FF/2018/8133 dated 10-MAY-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 and Cosmetics Rules 122DA and 122DAC, under the supervision of the following investigator mentioned below as per Protocol No.: BA1786032, Version No. 00, Protocol Date 08-MAY-2018 submitted to this Directorate.

Name of Investigator	Clinical Trial Site Address	Name and Address of the Ethics Committee
Dr. Mayur Barot	Cliantha Research Limited, 1st Floor, Silver Arcade, Near Ashwamegh III, Samrajya, Mujmahuda Road, Akota, Vadodara-390020, Gujarat, India	Sanjeevani Independent Ethics Committee, GF-28, 29 & 44, Avishkar Complex, Near. G.E.B. Colony, Old Padra Road, Vadodara-390015. EC Reg. No. ECR/57/Indt/GJ/2013/RR-16

Licensing Authority as defined in clause (b) of Rule 21, issue permission for conduct of clinical trial, subject to the following conditions further, namely:

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

(b) Approval of the Ethics Committee shall be obtained 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 to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with procedures prescribed in Schedule Y.
(f) In case of an injury or death during the clinical trial to the subjects of the Clinical Trial, 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) Submit complete report of clinical trials as per the approved protocol from the individual Investigator duly signed by him along with his observations/remarks on the drug.
(j) Indicate the date of commencement and conclusion of the clinical trial at each center (in case the study is multicentric)
(k) Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics Committees.
(l) 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.

(m) 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.

It is informed that all the amendments to Rule 122DAA, inclusion of Rule 122DAB, compensation matters etc. that are appended to the Drugs & Cosmetics Act & Rules, vide GSR 53 (E) dated 30.01.2013 and in Part X-A, after Rule 122DAB, Rule 122 DAC vide GSR 63 (E) dated 01.02.2013 are mandatory and binding.

Yours faithfully

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
Date: 2018.10.11 16:18:50 +05'30'

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