Protocol No: GENA-05, version 02 dated 17 Dec, 2012

(2)

38863/13/08/13

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
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File No: CT/151/12-DCG (I) Dated: 02/09/13

To,
M/s. Max Neeman Medical International Ltd.,
Max House, 1 Dr. Jha Marg,
Okhla – III, New Delhi- 110020.

Subject: A clinical trial with **Human-cl rh FVIII (250 IU, 500 IU, 1000 IU, 2000 IU)** (Protocol No: GENA-05 Version 02 dated 17-12 -12) – regarding.

Clinical Trial NOC No. GCT/04/13

Reference: Your letter no. MNI/GENA-05/12/07 dated 09/08/13 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 investigators mentioned below.

1. Dr. Dinesh Nayak, Kasturba Medical College, Manipal University, Manipal 576104, Karnataka.
2. Dr. Vijay Ramanan, Jehangir Clinical Development Centre, Jehangir Hospital Premises, 32 Sasoon Road, Pune-411001.

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 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

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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 ten 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. Before initiation of the study, you are required to obtain approval of Ethics Committee which is duly registered under the Provision of Drugs and Cosmetics Rules 1945.

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

Yours faithfully,

(Dr. G.N. Singh)
Drugs Controller General (India)