

20408/13.05.14

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
Te No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

File No: CT/208/12 - DCG (I)

Dated: 14/07/14

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

Subject: Permission for conducting a Phase IV clinical trial entitled "Immune Tolerance Induction, By Factor VIII Concentrate Containing Von Willebrand Factor, In Severe or Moderate Haemophilia A Patients with Inhibitors"- regarding.

Clinical Trial NOC No.:- GCT/33/14

Reference: - Your letter no. MNI/FCG-CNS-001/12/05 dated 13th May 2014 on the subject mentioned above.

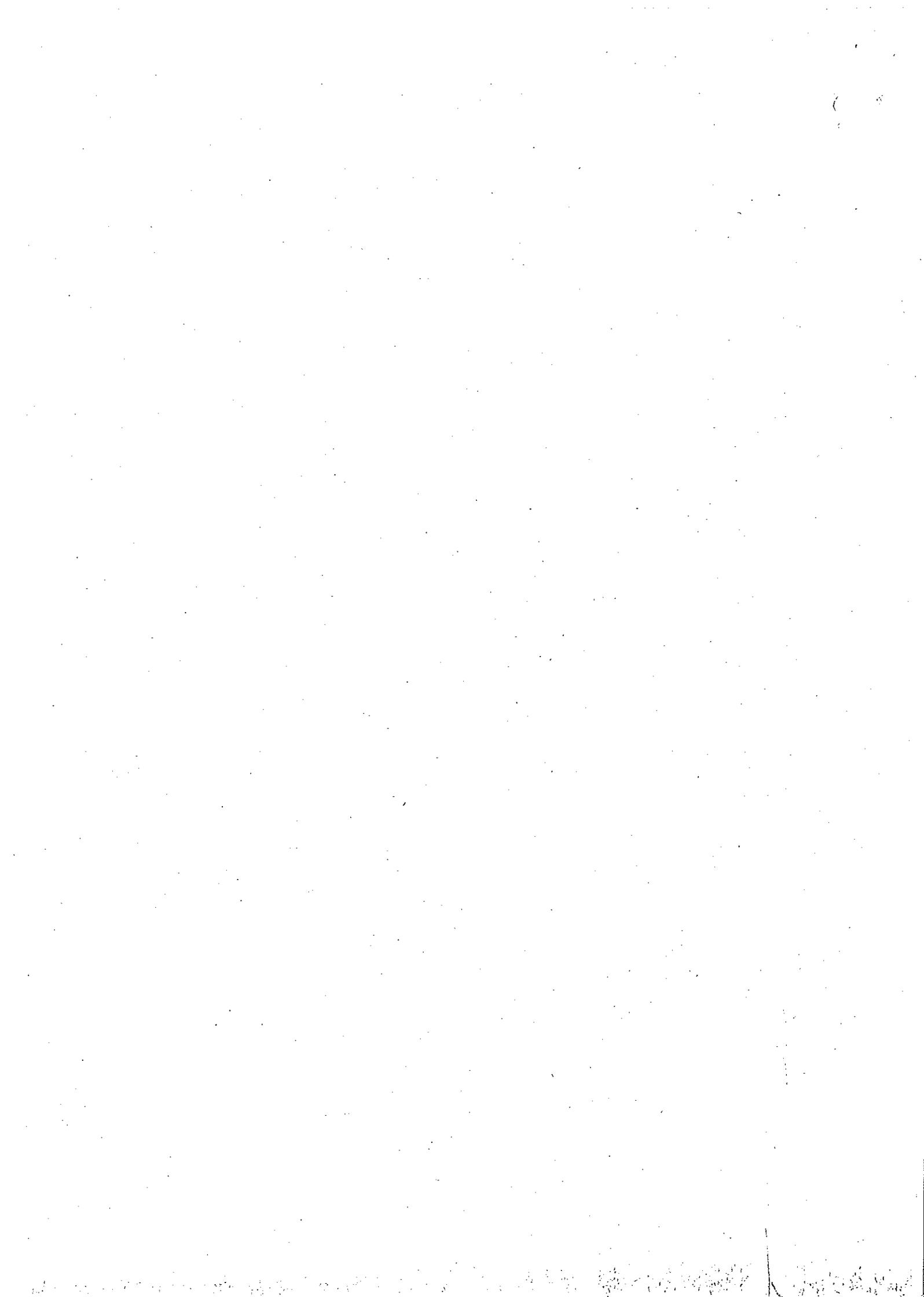
Sir,

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 investigators and as per the **Protocol No: FCG-CNS-001-Version 1.0 dated 30st April 2012** submitted to this Directorate.

1. Dr. Madatha Vijay Ramanan, Consultant Haematologist, Jehangir Clinical Development Centre Pvt. Ltd., Jehangir Hospital Premises, 32, Sassoon Road, Pune-411001, Maharashtra.
2. Dr. Naresh Kumar Gupta, Dept. of Medicine, Haemophilia Day-Care Centre, Ground Floor, New Medical Block, Lok Nayak Hospital & Maulana Azad Medical College, New Delhi- 110002.
3. Dr. Cecil R Ross, Prof. of Medicine, St. John's Medical College & Hospital, Dept. of Haematology, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka.
4. Dr. Tulika Seth, Associate Prof. Haematology, Room No. 5017, V Floor, Teaching Block, All India Institute of Medical Sciences, New Delhi-110029.

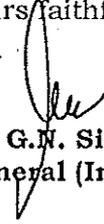
Kindly note that the clinical trial permission is subject to the following conditions:

- 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;



- 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. You are also informed that audio visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done duly adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. All the sponsors /investigators /institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate effect.
- 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.
- n. 50% of the clinical trial sites should be at Govt. Hospital/Medical Colleges. The sites should be geographically distributed across the country. Accordingly, you are required to apply to this directorate, for the inclusion of additional sites.

Yours faithfully,



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

