File No. ECR/635/Astha/Indt/GJ/2013

From:

The Drugs Controller General (India)
Directorate General of Health Services

New Delhi – 110 002
Dated: 07 AUG 2013

To,

The Chairman,
Ethics Committee,
Astha Independent Ethics Committee,
502, Shashvat Tower, Near Shyamal Row House-3/B,
Behind Dhananjay Tower, Satellite, Ahmedabad-380015,
Gujarat, India

SUB: - Ethics Committee Registration No. **ECR/ 88 /Indt/GJ/2013** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Dear Sir,

Please refer to your application no. Nil dated 19.06.2013 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby Registers the **ETHICS COMMITTEE, ASTHA INDEPENDENT ETHICS COMMITTEE** situated at **502, SHASHVAT TOWER, NEAR SHYAMAL ROW HOUSE-3/B, BEHIND DHANANJAY TOWER, SATELLITE, AHMEDABAD-380015, GUJARAT, INDIA** with Registration number **ECR/ 88 /Indt/GJ/2013** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. **The Ethics Committee shall review and approve only the study protocols and relate documents of Bioavailability/Bioequivalence studies of the approved drug molecules and also carry ongoing review of such studies.**
2. The Ethics Committee shall review and accord its approval to Bioavailability/Bioequivalence studies and also carry ongoing review of such studies at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well being of the trial subjects.
3. In the case of any serious adverse event occurring during Bioavailability/Bioequivalence studies, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.

4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to Bioavailability/Bioequivalence studies and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of Bioavailability/Bioequivalence studies.

5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions under Schedule Y, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

    For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

    i. Basic medical scientist (preferably one pharmacologist)
    ii. Clinician
    iii. Legal expert
    iv. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    v. Lay person from community