File No: BIO/Form44/FF/2018/11312
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road New Delhi - 110002
(Biological Division)

Dated: 29-JAN-2019

To

M/s Indian Council of Medical Research (ICMR),
National Institute of Cholera and Enteric Diseases,
P33 CIT Road Scheme XM Beliaghata Kolkata (India) - 700010

Subject: Permission for conducting a Phase IV clinical trial titled "Immunogenicity and Safety of Rotavac® and Rotasiil® Administered in an Interchangeable Dosing Schedule among Healthy Indian Infants: A Multicentric, Phase IV, Open-Labeled, Randomized, Controlled Trial"- regarding.

Reference: Your Application No. BIO/Form44/FF/2018/11312 dated 30-OCT-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 under the supervision of the following investigators mentioned in your letter and as per **Protocol No.: 1 Version No. 1.2 Dated: 11-DEC-2017** submitted to this Directorate.

CT No. CT- 01/2019

1. Dr. Ashish Bavdekar, KEM Hospital Research Center, Sardar Moodliar Road Rasta Peth, Pune-411011 Maharashtra, India.
2. Dr. Shanta Dutta, ICMR, National Institute of Cholera and Enteric Diseases, P-33, CIT Scheme XM, Beliaghata, Kolkata –700 010, West Bengal, India.
3. Dr. Sudhir Babji, The Wellcome, Trust Research Laboratory Department of Gastrointestinal Sciences Christian Medical College Ida Scudder Road, Vellore, Tamil Nadu Vellore 632 004, Tamil Nadu, India.

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 duly registered with the office of DCG (I) shall be obtained before initiating the clinical trial.
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 Institutional Ethics committees.

j. 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.

k. An audio - video recording of the informed consent process in case of vulnerable subjects in clinical trials 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.

l. 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.

m. **To submit the Investigator's Brochure to this office before initiation of the said clinical trial.**

n. **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.**

o. **Only CDL, Kasauli Certified batches shall be used in the clinical trial.**

Yours faithfully,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
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Date: 2019.04.08 17:12:40 +05'30'

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