File No: BIO/CT/25/000138
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

The Drugs Controller General, India
Directorate General of Health Services,

To

M/s Human Biologicals Institute
(A division of Indian Immunologicals Limited),
Sy. No. 281-284 & 321, Biotech Park Phase III,
Karkapatla (V), Markook Mandal, Siddipet District,
Telangana (India) – 502281

Subject: Permission for conducting a clinical trial titled "A First-in-Human Randomized, Double Blind, Placebo-Controlled Phase I Study in Healthy Indian Adults to Evaluate the Safety, Reactogenicity and Immunogenicity of inactivated KFD vaccine developed by the Human Biologicals Institute" [Protocol no: KFD-001, Version: 5.5, dated 07.08.2025] – regarding.

Reference: Your Application No. BIO/CT04/FF/2025/51738 dated 05.09.2025 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2025/51738 dated 05.09.2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Inactivated Kyasanur Forest Disease (KFD) Vaccine" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.11.12 10:57:37 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

File No: BIO/CT/25/000138
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Sy. No. 281-284 & 321, Biotech Park Phase III, Karkapatla (V), Markook Mandal, Siddipet District, Telangana (India) - 502281, Telephone No: 919948664140, FAX: 919948664140, E-Mail: IILRA@INDIMMUNE.COM to conduct clinical trial of the new drug or investigational new drug as per the protocol number KFD-001, Version: 5.5, dated 07.08.2025 in the below mentioned clinical trial sites.

CT No.: CT- 22/2025

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Inactivated Kyasanur Forest Disease (KFD) Vaccine</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Injectable (Intramuscular), Sterile suspension in USP type 1 glass vials.</td></tr>
<tr><td>Composition:</td><td>Each 0.5 mL contains:
<table>
<tr><th>Component</th><th>Quantity/0.5 mL</th></tr>
<tr><td>Active Ingredient</td><td></td></tr>
<tr><td>Inactivated Kyasanur Forest Disease (KFD) Antigen</td><td>≥ 18.00 µg</td></tr>
<tr><td>Inactive Ingredients</td><td></td></tr>
<tr><td>Aluminium Hydroxide gel [Al $(OH)_3$]</td><td>≤ 1.25 mg</td></tr>
<tr><td>Thiomersal</td><td>0.01 % w/v</td></tr>
<tr><td>Phosphate Buffer Saline (PBS)</td><td>q.s. to 0.5 mL</td></tr>
</table></td></tr>
<tr><td>Indication(s):</td><td>For prevention of Kyasanur Forest Disease.</td></tr>
</table>

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	Manipal Academy of Higher Education, Kasturba Medical College, Manipal, Udupi, Karnataka -576104, India.	Manipal Academy of Higher Education (MAHE) Ethics Committee, Kasturba Medical College, Manipal, Udupi, Karnataka -576104, India. [ECR/191/Inst/KL/2013/RR-24]	Dr. Muralidhar Varma, [MD in General Medicine]
2.	JSS Medical College and Hospital, Mysuru, Karnataka-570004, India	Institutional Ethics Committee JSS Medical College, JSS Medical College, JSS Hospital, Mysore, Sri Shivarathreeshwara Nagara, Mysuru (Mysore), Karnataka - 570015, India. [ECR/387/Inst/KA/2013/RR-22]	Dr. Venkatesh C.R. [MD in General Medicine]

In addition to point 3, the permission is subject to following conditions:

1. The clinical trial should be conducted as per approved protocol titled “A First-in-Human Randomized, Double Blind, Placebo-Controlled Phase I Study in Healthy Indian Adults to Evaluate the Safety, Reactogenicity and Immunogenicity of inactivated KFD vaccine developed by the Human Biologicals Institute” [Protocol no: KFD-001, Version: 5.5, dated 07.08.2025].

2. The formulation intended to be used in the Phase-I clinical trial shall be manufactured under GMP Conditions.
3. Only CDL, Kasauli certified batches shall be used in the Phase-I clinical trial.
4. To submit Ethics Committee approval for the clinical trial.
5. To submit CRO registration details once obtained from the CDSCO.
6. To submit leachability study report of PETG (Polyethylene terephthalate glycol) bottle used for storage of Inactivated KFD antigen (Drug substance).
7. To submit CAPA compliance verification report of earlier joint inspection dated 25.09.2025 to 26.09.2025 of proposed facilities at M/s. Human Biological Institute, Karkapatla, Telangana to manufacture the applied Inactivated Kyasanur Forest Disease (KFD) Vaccine.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: