File

No.: <u>VET-13014(19)/1/2024-eoffice</u>

Government of India

## Directorate General of Health Services Central Drugs Standard Control Organisation (Veterinary Division)

FDA Bhawan, Kotla Road, New Delhi-110 002, India Dated: 2 SEP 2024

## **CIRCULAR**

Subject: Online application in Form-44 for issuance of New Drug permission of Bulk (API) drugs/vaccines in Form 45A/46A and finished formulation in Form-45/46 & Field Trial Permission for Veterinary purpose only-reg.

In order to streamline the regulatory submission procedure, the submission of application for issuance of New Drug permission of Vaccines/ Drugs for Bulk (API) in Form-45A/46A and finished formulation in Form-45/46 and Field Trial Permission is now functional on online system of SUGAM Portal (www.cdscoonline.gov.in). The applicants seeking such certificate/approval/permission shall apply through online portal as per the checklist in the developed modules.

The facility of offline submission of applications in Form-44 in hard copy/through e-office may not be available for processing from 16th August 2024.

(Dr. Rajeev Singh Raghuvanshi) Drugs Controller General (Inida)

To,

- 1. All Stakeholders through CDSCO website.
- 2. State/UT Licenseing Authorities (for information and necessary action)
- 3. CDAC Team.