

Recommendations of the SEC (Veterinary) made in its 01st/25 meeting held on 24.02.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Veterinary Division			
1.	F.No.:Vet-11011(16)/01/2023-2102 Afoxolaner 11.3mg/28.3 mg/68 mg/136 mg chewable tablets.	M/s Boehringer-Ingelheim India Pvt. Ltd	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit the following and present the same in the next SEC meeting. a) Details of safety and efficacy data, along with field trial data. b) Justification for the selection of the number of animals in groups used in the study, along with the approved protocol for the field trial. c) Justification data for products used in male dogs. However, the firm has not included the male dogs in the study. d) Post marketing surveillance data of the drugs. e) Data on potential accumulation of drugs in the body due to long-term use must be submitted including data on liver toxicity (hepatotoxicity) and kidney toxicity (renal toxicity). f) What are the specific indications for use in pre-mating, mating, pregnant, and lactating dogs.
2.	F.No.: Vet-11011(16)/17/2024-12581 FDC of the Afoxolaner 9.37mg/18.75mg/37.5 mg/75mg/150mg and Milbemycin oxime 1.87mg/3.75mg/7.5mg/15mg/30mg chewable tablets.	M/s Boehringer-Ingelheim India Pvt. Ltd	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit the following and present the same in the next SEC meeting. a) Details of safety and efficacy data, along with field trial data. b) Justification for the selection of the number of animals in groups used in the study, along with the approved protocol for the field trial. c) Justification data for products used in male dogs. However, the firm has not included the male dogs in the study. d) Post marketing surveillance data of the drugs. e) Data on potential accumulation of drugs in the body due to long-term use

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			must be submitted including data on liver toxicity (hepatotoxicity) and kidney toxicity (renal toxicity)
3.	F.No.12-10/ Boehringer/2023-VD FDC of Esafoxolaner(1.2% w/v) , Eprinomectin(0.4% w/v) , Praziquantel(8.3% w/v) Spot on solution	M/s Boehringer- Ingelheim India Pvt. Ltd	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit the following and present the same in the next SEC meeting. a) Rationale for the proposed FDC (justification for combining drugs with different half-lives) including Pharmacokinetic interactions if any of all the drugs. b) Data on potential accumulation of drugs in the body due to long-term use including data on liver toxicity (hepatotoxicity) and kidney toxicity (renal toxicity). c) Justification for the variation in the number of animals selected for the study d) What are the causes of pupil dilation, and how long does it last and time for the reversal of pupil dilation. e) Submission of multiple-dose toxicity study data is required.
4.	F.No.: Vet- 11011(11)/ 21/2024- 7599 and Physical F.No.12- 21/Zoetis/2022-VD Oclacitinib Maleate Chewable Tablet 5.4mg and Oclacitinib Maleate Chewable Tablet 16mg	M/s Zoetis India Ltd.	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit to CDSCO, the complete data of the drug including BE Study results for further deliberation in the next SEC meeting.
5.	F.No.: Vet- 11011(11) / 53/2024-14209 and Physical F.No.12- 27/Intervet/2022-VD Fluralaner Spot on solution for dogs and cats (Bravecto)	M/s Intervet India Pvt. Ltd.	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit to CDSCO, the complete data of the drug including BE Study results for further deliberation in the next SEC meeting.
6.	F.No. VET 11012(11)/23/2024- 14248 Physical F.No. FDC/MF/20/000002	M/s Akums Drugs & pharmaceutical Ltd.	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit the following and present the same in the

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	(VD) Amoxicillin 3gm + Clavulanic Acid 600mg		next SEC meeting. a) In vitro study data for efficacy, susceptibility and minimum inhibitory concentration against the animal pathogens. b) Justification for dose selection in target animals, maximum dose, schedule of dosing and withdrawal period.
7.	F.No.VET-11012(11) /11/2024-10636 and Physical F.No. FDC/MF/20/000006 VET Cefoperazone Sodium IP(Sterile) Eq to Anhydrous Cefoperazone 3GM+ Sulbactam Sodium USP (Sterile) to Anhydrous sulbactam 1.5gm/ ML Injection	M/s Akums Drugs and Pharmaceuticals Ltd	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit the following and present the same in the next SEC meeting. a) In vitro study data for efficacy, susceptibility and minimum inhibitory concentration against the animal pathogens. b) Justification for dose selection in target animals, maximum dose, schedule of dosing and withdrawal period.
8.	F.No VET- 11011(11)/33/2024- 10731 Deslorelin Acetate 4.7mg subcutaneous implant for female Dogs & Male Cats Implants: White to pale yellow cylindrical implant	M/s Virbac Animal Health	The firm presented the proposal before the SEC committee. After detailed deliberation, the committee recommended that the firm should submit the following details in the revised label and package insert and present the same in the next SEC meeting. a) Clear indications, contraindications, data on implant duration and withdrawal complications. b) Target animal safety study data. c) Justify the withdrawal effects of the product concerning the reversibility of reproductive organ size and reproductive behavior and productivity.