Felix Pharmaceuticals Pvt. Ltd.

25-28, North Wall Quay, Dublin 1
Republic of Ireland

Suitability Petition

Felix Pharmaceuticals Pvt. Ltd.
25-28, North Wall Quay
Dublin 1, Republic of Ireland

I. Citation: Felix Pharmaceuticals Pvt. Ltd. submits this petition under Section 512(n)(3) of the Federal Food, Drug and Cosmetic Act.

II. Action Requested: We request permission to file an application for an abbreviated new animal drug application (ANADA) for a generic Oral solution for Maropitant Citrate that differs from the pioneer product, CERENIA® Tablets, sponsored by Zoetis Inc. under NADA 141-262. The RLNAD is approved as a tablet and the proposed generic product is an oral solution. The route of administration as well as the dosage of active per pound of body weight will be the same for the proposed generic product as the parent product.

III. Statement of Grounds: Under Section 512(n)(3)(A), if a person wants to submit an abbreviated application for a new animal drug "whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug", such person shall submit a petition to the Secretary seeking permission to file such an application.

Permission is sought to change the oral dosage form from a tablet to an oral solution. The proposed oral solution will be bioequivalent to the pioneer product. The route of administration remains the same. All excipients proposed to be used in the oral solution are already used in other oral dosage form product approved for Dogs. Therefore, the different oral dosage form will not adversely affect the safety and effectiveness of Maropitant Citrate.

The pioneer product is available as a single scored, peach colored oval tablets available in 4 strengths, namely 16 mg, 24 mg, 60 mg and 160 mg. The oral solution will be supplied with a strength of 40 mg/mL. The solution will be filled in 15 mL and 30 mL bottle and will be provided with two calibrated syringes of 1.0 mL and 5.0 mL. The proposed strength of oral solution coupled with provided calibrated syringe allows proper administration of drug product to Dogs covering the dosage range suggested by pioneer product as depicted below.

Proposed Generic product		Equivalent strength of Pioneer product
Strength	Quantity to be administered	
40 mg/mL	0.4 mL	16 mg Tablet
	0.6 mL	24 mg Tablet
	1.5 mL	40 mg Tablet
	4.0 mL	160 mg Tablet

Administration of oral solution will provide a convenient alternative to the currently approved dosage form with enhanced ease of administration. Since, calibrated syringes are used to administer oral solution, dosing can be adjusted according to the actual body weight of Dog. This provides an advantage over tablet, for which the actual dose administered will also depend on the strength of tablet.

IV. Environmental Impact: Felix Pharmaceuticals Pvt. Ltd. requests that this petition be considered for categorical exclusion under 21 CFR 25.30(h). We confirm that no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

V. Economic Impact: An economic impact statement will be provided if requested after review of this petition.

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VI. Certification: Felix Pharmaceuticals Pvt. Ltd. certifies that this suitability petition contains all information known to them that is unfavorable to the petition.

VII. Labeling: A copy of pioneer labelling is enclosed. For the package insert, the only changes proposed will pertain to the product name, strength, the manufacturer, dosage and administration, how supplied and storage condition sections. Other aspects of labeling will differ only in the product name, strength, the manufacturer, dosage and administration, how supplied and storage condition sections. Copies of the pioneer package insert and a draft of the proposed package insert for the Felix Pharmaceuticals Pvt. Ltd. generic oral solution are provided as Attachments 1 and 2 to this petition.

FELIX PHARMACEUTICALS PVT. LTD. Reg. No. 555453

Date: 10 July 2024

Signature:
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