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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061,
Rockville MD 20852
USA

August 27, 2013

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.30 as provided for in the Federal Food, Drug and Cosmetic Act Chapter V: Drugs and Devices, Section 512 §360b (n)(3)(A) on behalf of Parnell Technologies Pty Ltd, Unit 4, 476 Gardeners Road, Alexandria, NSW 2015, Australia.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration allow for the sponsor's animal drug product Gonabreed (gonadorelin 100 µg/mL), ANADA 200-541 be amended to delete one route of administration (intravenous) from the currently approved routes of administration (intramuscular, intravenous) for the treatment of cystic ovaries in dairy cattle.

The approved reference listed drug, Merial's Cystorelin® (gonadorelin diacetate tetrahydrate 50 µg/mL (equivalent to 43 µg/mL gonadorelin), NADA 098-379 details both intramuscular and intravenous administration for the treatment of cystic ovaries in dairy cattle.

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an ANADA for a new animal drug that differs in route of administration from that of a listed drug, provided the FDA has approved a petition that proposed the filing of such an application.

Under provisions of the Federal Food, Drug, and Cosmetic Act, Section 512(n)(3)(A) -

If a person wants to submit an abbreviated application for a new animal drug—

> *(A) 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.

This Suitability Petition qualifies under the provisions of the Federal Food, Drug, and Cosmetic Act, Section 512(n)(3)(A) in that permission is sought to remove one route of administration such that the route of administration differs from that detailed for the pioneer product. The pioneer product details two routes of administration (intramuscular, intravenous) whereas under this petition it is proposed that Gonabreed detail only one route of administration (intramuscular).

The proposed removal of the intravenous route of administration strength does not pose questions of safety or effectiveness because the product will continue to be indicated for intramuscular administration in identical manner to the pioneer product for the treatment of cystic ovaries.

C. Environmental Impact

A categorical exclusion for an environmental impact assessment on the action requested is requested under 21 CFR 25.33(a)(5) *Drugs intended for use under prescription or veterinarian's order for therapeutic use in terrestrial species*. Gonabreed is approved for use only by or on the order of a licensed veterinarian.

D. Economic Impact

The petitioner does not believe that an Economic Impact analysis of this action is applicable in this case, however will agree to provide such an analysis upon request by the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

For the foregoing reasons, the undersigned requests that the Commissioner approve this petition and find that an amendment to the ANADA is suitable for submission.

Yours faithfully
Parnell Technologies Pty Ltd

Fenella Cochrane

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