DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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September 11, 2013

Fenella Cochrane BVSc
Director, Scientific Affairs
Parnell Technologies Pty Ltd
9401 Indian Creek Parkway, Suite 1170
Overland Park, KS 66210

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Agency 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, was received by this office on 09/03/2013. It was assigned docket number FDA-2013-P-1078/CP1, and it was filed on 09/03/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)