FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
La Haute Marche
Javené BP 90203
35302 FOUGERES cedex
FRANCE

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Suifertil 4 mg/ml oral solution for pigs

Date: 22 April 2013

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0199/001/DC
Name, strength and pharmaceutical form	Suifertil 4 mg/ml oral solution for pigs
Applicant	ANIMEDICA GmbH Im Südfeld 9 48308 Senden-Bösensell Germany
Active substance(s)	Altrenogest
ATC Vetcode	QG03DX90
Target species	Pigs (sexually mature gilts)
Indication for use	Synchronisation of oestrous in sexually mature gilts

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	21/11/2012
Concerned Member States for original procedure	AT, DE, HU, NL, PL, RO, ES, UK

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 4.0 mg/ml of altrenogest and excipients butylhydroxianisole, butylhydroxytoluene and soya-bean oil refined.

The container is an aluminium bottle closed with screw cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is altrenogest, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material.
Batch analytical data demonstrating compliance with this specification have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

G. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The test product is bioequivalent to the reference product, REGUMATE, marketed by INTERVET. An exemption from the requirement to provide a bioequivalence study was accepted as formulations of the tested and the reference products are similar.

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

User Safety

The formulations of the tested and the reference products are similar. Warnings and precautions of the reference product SPC have been applied to the tested product SPC and are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant has provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Residue Studies

No residue studies were submitted which is acceptable since the tested and the reference products are bioequivalent and they are intended to be used via oral route.

MRLs

a. active substances

Currently, the active substance, altrenogest, is included in table 1 of the MRL regulation 37/2010, as follows,

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Altrenogest	Altrenogest	Porcine	1 µg/kg 0,4 µg/kg	Skin and fat Liver	Only for zootechnical use and in accordance with the provisions of Directive 96/22/EC.	Agents acting on the reproductive system
		Equidae	1 µg/kg 0,9 µg/kg	Fat Liver		

b. excipients

Excipients	MRL status
Butylhydroxyanisole (E320)	No MRL required
Butylhydroxytoluene (E321)	No MRL required
Soya-bean oil	No MRL required

Withdrawal Periods

The withdrawal periods of the reference product will be applied to the tested product: Meat and offal: 9 days.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided a tolerance study which is acceptable because the tested product and the reference product are bioequivalent and their formulations are similar.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims of the tested product are based on the reference product documentation.

V. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.