

BIONICHE

ANIMAL HEALTH USA, INC.

November 4, 2004

Documents Management Branch (HFA-305), Room 1061
Food and Drug Administration,
5630 Fishers Lane,
Rockville, MD USA
20852

***Suitability Petition
Serum gonadotropin and chorionic gonadotropin for injection***

Dear Sir or Madam:

Please find enclosed a suitability petition for Agency review and action. Bioniche Animal Health USA, Inc., is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic serum gonadotropin and chorionic gonadotropin for injection that differs from the pioneer product (P.G. 600@; NADA 140-856) in packaging presentation.

Your review of the enclosed petition would be greatly appreciated.

Please feel free to contact me at (613) 966-8058 should have any questions or require further information.

Sincerely,



Cindy Hickey
V.P. Corporate Quality & Regulatory Affairs
Bioniche Life Sciences Inc.

Enclosure

2004P.0489

CP1

Suitability Petition

Bioniche Animal Health USA, Inc. Serum Gonadotropin and Chorionic gonadotropin for injection November 4, 2004

The undersigned submits this petition under Section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of an application for a generic serum gonadotropin and chorionic gonadotropin for injection that differs from the pioneer product (P.G. 600®; NADA 140-856) in packaging and presentation of the active ingredients.

Action Request

We are requesting that the Commissioner permit the filing of an Abbreviated New Animal Drug Application (ANADA) for serum gonadotropin and chorionic gonadotropin for injection (trade name to be determined). Our proposed product differs from the pioneer product as follows:

Pioneer Product

Trade Name

P.G. 600® (NADA 140-856)

Active ingredients

Serum gonadotropin, chorionic gonadotropin

Dosage form

Injection

Strength

SINGLE DOSE VIALS - Five vials containing white freeze dried powder, plus five vials containing sterile diluent. When reconstituted, each single dose vial (5 mL) contains 400 IU serum gonadotropin and 200 IU chorionic gonadotropin (equivalent to 200 USP Units chorionic gonadotropin).

FIVE DOSE VIALS - One vial containing white freeze dried powder, and one vial containing sterile diluent. When reconstituted, the five dose vial (25 mL) contains 2000 IU serum gonadotropin and 1000 IU chorionic gonadotropin (equivalent to 1000 USP Units chorionic gonadotropin).

Sponsor

Intervet, Inc.

Dosage

One dose (5 mL) of reconstituted P.G. 600®, containing 400 IU serum gonadotropin and 200 IU chorionic gonadotropin, should be injected into the gilt or sow's neck behind the ear with a 20G X 1.5 inch hypodermic needle. Prepuberal gilts should be injected when they are selected for addition to the breeding herd. Sows should be injected at weaning during periods of delayed return to post-weaning estrus

Proposed Drug Product

Trade Name

To be determined.

Active ingredients

Serum gonadotropin, chorionic gonadotropin

Dosage form

Injection

Strength

FIVE DOSE VIALS – Two vials containing white freeze dried powder, and one vial containing sterile diluent. One five dose vial contains 2000 IU serum gonadotropin and one five does vial contains 1000 IU chorionic gonadotropin (equivalent to 1000 USP Units chorionic gonadotropin). The vial of sterile diluent is used to reconstituted one of the vials of drug and that reconstituted vial is used to reconstintued the second vial of drug. The resulting reconstituted vial contains 25 mL of solution containing 80 IU/mL of serum gonadotropin and 40 IU/mL of chorionic gonadotropin.

Sponsor

Bioniche Animal Health USA, Inc.

Dosage

One dose (5 mL) of reconstituted product, containing 400 IU serum gonadotropin and 200 IU chorionic gonadotropin, should be injected into the gilt or sow's neck behind the ear with a 20G X 1.5 inch hypodermic needle. Prepuberal gilts should be injected when they are selected for addition to the breeding herd. Sows should be injected at weaning during periods of delayed return to post-weaning estrus

Statement of Grounds

The proposed generic product contains the same active ingredient and will be labeled with the same indications, precautions and warnings as the approved pioneer product. The route of administration and the dosage form are the same for the generic and pioneer products. The strength of the active ingredients are the same for the generic and pioneer products. The packaging presentation differs from the pioneer product in that the pioneer product presents its active ingredients as combined in one vial. The proposed generic product will present its active ingredients in two separate vials.

While the proposed generic product differs in packaging presentation of the active ingredients as compared to the pioneer product, the reconstituted product and therefore the dose administered per animal will be the same as that of the pioneer product.

Environmental Impact

In accordance with 21 CFR 25.33(a)(1), Bioniche Animal Health USA, Inc. requests a categorical exclusion from the requirement to file an environmental impact assessment for this action, as the generic drug will be marketed under the same conditions of approval as the previously approved animal drug.

Economic Impact

Information pertaining to the economic impact of this petition will be submitted if requested by the commissioner.

Certification

Bioniche Animal Health USA, Inc. certifies that this suitability petition contains all information know to them that is unfavourable to the petition.

Cindy Hickey
Cindy Hickey
V.P. Corporate Quality & Regulatory Affairs
Bioniche Life Sciences Inc.

5/1/04 4/04
Date