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(302) 934-4385

16 March 2004

Dr. Lonnie Luther, Staff Chief (HFV-102)
C/O: Dockets Management Branch, HFA-305
Room 1061
5630 Fishers Lane
Food and Drug Administration
Rockville, MD 20852

RE: SUITABILITY PETITION FOR REVIEW AND ACTION – FLORFENICOL INJECTABLE SOLUTION

Dear Dr. Luther:

Please find enclosed a suitability petition for Agency review and action. Intervet Inc. is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic florfenicol injectable solution that differs from the pioneer product (Nuflor[®]; NADA 141-063) in strength (i.e., concentration) of the active ingredient.

Your timely review of the enclosed petition will be greatly appreciated.

Please feel free to call (302-934-4385) or e-mail (lee.whaley@intervet.com) me should you have any questions or if I can be of assistance.

Sincerely,

A handwritten signature in cursive script that reads "S. Lee Whaley".

S. Lee Whaley, MS
Manager, Regulatory Affairs – Pharmaceuticals
Intervet Inc.

Enclosure

2004P 0136

CPI

Suitability Petition

**Intervet Inc.
Florfenicol Injectable Solution for Cattle
16 March 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 florfenicol injectable solution formulation that differs from the pioneer product (Nuflor[®]; NADA 141-063) in strength of the active ingredient in the proposed drug product.

Action Requested

We are requesting that the Commissioner permit the filing of an Abbreviated New Animal Drug Application (ANADA) for an injectable florfenicol solution for cattle (trade name to be determined) that differs in strength from the pioneer product. The ANADA will include a bioequivalence study. Our proposed product differs from the pioneer product as follows:

Pioneer Product**Trade name**

Nuflor[®] Injectable Solution (NADA 141-063)

Strength

30% florfenicol (wt/vol). Each milliliter contains 300 mg florfenicol.

Sponsor

Schering-Plough Animal Health Corporation.

Dosage

Nuflor injectable solution should be administered by intramuscular injection to cattle at a dose of 20 mg/kg body weight (3 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, Nuflor injectable solution can be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs).

Proposed Drug Product

Trade name

To be selected

Strength

45% florfenicol (wt/vol). Each milliliter contains 450 mg florfenicol.

Sponsor

Intervet Inc.

Dosage

The florfenicol injectable solution should be administered by intramuscular injection to cattle at a dose of 20 mg/kg body weight (2 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, the injectable solution can be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (4 mL/100 lbs).

Statement of Grounds

The proposed generic product contains the same active ingredient and will be labeled with the same indications, recommended dose rates, precautions and warnings as the approved pioneer product. The route of administration (intramuscular or subcutaneous injection) and the dosage form (injectable solution) are the same.

An injectable florfenicol solution formulation that has a greater strength of florfenicol than the pioneer product will be successful in administering the required amount of the antibiotic in a reduced volume, potentially decreasing the number of injection sites. While this product has a change in strength of the active ingredient compared to the pioneer, the dose of florfenicol administered per kilogram body weight is the same as the pioneer product.

Environmental Impact

Intervet Inc. requests a categorical exclusion under 21 CFR 25.33(d)(5) from the requirements to file an environmental impact assessment, as the drug is intended for use under veterinary prescription or veterinarian's order for therapeutic use in a terrestrial species.

Economic Impact

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

Differences Between Pioneer and Proposed Generic Product Labeling

The changes in the labeling noted below may not be placed in the same areas as they are located on the pioneer product. The changes noted will be reflected in the proposed drug product's labeling in an appropriate manner so that it is clear and readily understood by the end-user. Please see the attached proposed labeling.

References to "Nuflor[®] Injectable Solution" will be changed to "florfenicol" or to the new brand name as appropriate throughout the labeling.

The Nuflor name and logo will be removed and replaced with the new brand name and logo throughout the labeling.

References to "300 mg/mL" will be changed to indicate the product contains "450 mg/mL" florfenicol.

The product number will be changed.

The NADA number will be changed.

The sponsor information will be changed.

Under Description:

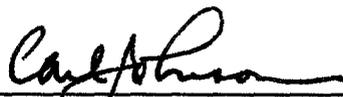
Changes in the formulation constituents of the pioneer will be appropriately reflected in the generic product labeling. Each milliliter will contain "450 mg of florfenicol".

Under Dosage and Administration:

The text of this section of the label will be changed to reflect the 450 mg/mL formulation and 2 mL/100 lbs or 4 mL/100 lbs dosage, as appropriate.

Certification

Intervet Inc. certifies that this suitability petition contains all information known to them that is unfavorable to the petition.



Carl K. Johnson, AM, DVM
Director, Product Development and
Regulatory Affairs – Pharmaceuticals

16 Mar 04

Date