Approval Date: April 2, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 141-063

B. Sponsor

Schering-Plough Animal Health Corporation
Schering-Plough Corporation
P.O. Box 529
Kenilworth, New Jersey 07033

C. Proprietary Name

NUFLOR® Injectable Solution

D. Established Name

florfenicol

E. Dosage Form

NUFLOR® Injectable Solution is a sterile non-aqueous solution available in 100-, 250-, and 500-mL glass vials. Each milliliter contains 300 mg florfenicol. NUFLOR® Injectable Solution should be stored at controlled room temperature (15 to 30 °C or 59 to 86 °F). Protect from from freezing.

F. Dispensing Status

This is a prescription product and includes the caution statement as follows: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

G. Dosage Regimen

NUFLOR® Injectable Solution should be administered by intramuscular injection to cattle at a dose of 20 mg/kg body weight (3 mL/100 lb). A second dose should be administered 48 hours later. Do not inject more than 10 mL at each site. The injection should be given only in the neck musculature.

H. Route of Administration

NUFLOR® Injectable Solution should be administered by intramuscular injection in the neck.

I. Indication

NUFLOR® Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.

J. Effect of Supplement

Label changes to standardize the veal calf residue warning and remove a graphic box from the Warnings section.

II. EFFECTIVENESS

The effectiveness of florfenicol in treating Bovine Respiratory Disease disease has previously been established in NADA 141-063. The label revisions will have no effect on the product efficacy previously established.

III. TARGET ANIMAL SAFETY

The safety of florfenicol has previously been demonstrated in NADA 141-063. The label revisions will not affect the safety of the product as previously established.

NUFLOR® Injectable Solution is indicated for the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.

The safety of food derived from cattle treated with florfenicol has been previously demonstrated in NADA 141-063. The label revisions will not affect human food safety as previously established.

In 1992 CVM sent a letter to sponsors directing them to add a standard veal warning statement to the labeling of products that were approved for use in calves and cattle, but had no human food safety data describing tissue residue depletion in pre-ruminating calves. The original approval for NADA 141-063 included some variations in the veal warning language in the RESIDUE WARNINGS section of the label. This supplemental application makes the language standard as follows.

"A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal."

The original approval for NADA 141-063 included a graphic box surrounding the WARNINGS section of the labeling. According to 21 CFR 201.57(e), use of a "black box" is normally reserved for adverse reactions associated with use of the drug product that may result in death or serious injury. Since no such reactions are known to be associated with florfenicol, the label has been revised to remove this box.

IV. AGENCY CONCLUSIONS

The two minor label revisions submitted in support of this supplemental NADA comply with the requirements of Section 512 of the Food, Drug, and Cosmetic Act and Part 514 of the implementing regulations.

According to the Center's supplemental approval policy, 21 CFR 514.106(b)(2)(ix), this is a Category II change. The approval of these changes is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a re-evaluation of the safety and effectiveness data in the parent application.
FDA has determined under 21 CFR 25.33 (see 62 FR 40570, 40596, July 29, 1997) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

NUFLOR® Injectable Solution is under U.S. patent number 5,082,863, which expires January 21, 2009.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.