Approval Date: October 28, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 009-576

SYNOVEX C and SYNOVEX S
(Progesterone and Estradiol Benzoate)

This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.

Sponsored by:

Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501

FREEDOM OF INFORMATION SUMMARY

SYNOVEX C Ear Implant for Suckling Beef Calves and SYNOVEX S Ear Implant for Steers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

a. File Number:	NADA 009-576
b. Sponsor:	Fort Dodge Animal Health Division of Wyeth 800 Fifth St. NW. Fort Dodge, IA 50501 Drug Labeler Code: 000856
c. Established Names:	Progesterone and Estradiol Benzoate
d. Propriety Names:	SYNOVEX C and SYNOVEX S
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.1940
f. How Supplied:	SYNOVEX C: Each box contains 2 or 10 foil pouches each containing 1 cartridge belt with 10 doses. Each implant dose consists of 4 pellets containing 100 mg progesterone and 10 mg estradiol benzoate. SYNOVEX S: Each box contains 10 foil pouches each containing 1 cartridge belt with 10 doses. Each implant dose consists of 8 pellets containing 200 mg progesterone and 20 mg estradiol benzoate.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	SYNOVEX C: 100 mg progesterone. 10 mg estradiol benzoate. SYNOVEX S: 200 mg progesterone. 20 mg estradiol benzoate.
i. Route of Administration:	Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.

j. Species/Class:	Suckling beef calves and steers fed in confinement for slaughter
k. Recommended Dosage:	SYNOVEX C: One implant containing 100 mg progesterone and 10 mg estradiol benzoate. SYNOVEX S: One implant containing 200 mg progesterone and 20 mg estradiol benzoate. May be re-implanted at approximately 70 days.
l. Pharmacological Category:	Steroid hormones
m. Indications:	SYNOVEX C: For increased rate of weight gain SYNOVEX C is recommended for use in suckling beef calves (at least 45 days of age) up to approximately 400 pounds of body weight. SYNOVEX C is also recommended for improvement in rate of weight gain in steers weighing greater than 400 pounds and fed in confinement for slaughter when used as part of a re-implant program in which an initial SYNOVEX C implant is followed at approximately 70 days by SYNOVEX S. SYNOVEX S: For increased rate of weight gain and improved feed efficiency in steers weighing 400 pounds or more. For additional improvement in rate of weight gain in steers fed in confinement for slaughter, SYNOVEX S may be used as part of a re-implant program where an initial SYNOVEX C or SYNOVEX S implant is followed by SYNOVEX S at approximately 70 days.
n. Effect of Supplement:	This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

2. DRUG EFFECTIVENESS:

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for SYNOVEX C and SYNOVEX S (NADA 009576).

3. TARGET ANIMAL SAFETY:

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for SYNOVEX C and SYNOVEX S (NADA 009576).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for SYNOVEX C and SYNOVEX S (NADA 009576).

5. AGENCY CONCLUSIONS:

The information submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change 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 reevaluation of the safety and effectiveness data in the parent application.

No patent information was submitted with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

SYNOVEX C 20 Dose Carton Label
SYNOVEX C 20 Dose Package Insert (Front and Back)
SYNOVEX C 100 Dose Carton Label
SYNOVEX C 100 Dose Package Insert (Front and Back)
SYNOVEX S Carton Label
SYNOVEX S Package Insert (Front and Back)