**FREEDOM OF INFORMATION SUMMARY**
**FOR**
**SYNOVEX® C AND SYNOVEX® S**
**(ESTRADIOL BENZOATE & PROGESTERONE)**

## 1. GENERAL INFORMATION

NADA Number: 9-576

Sponsor: Fort Dodge Animal Health
9401 Indian Creek Parkway
Overland Park, KS 66210

Generic Name: Estradiol benzoate and progesterone

Trade Names: Synovex® C and Synovex® S

Marketing Status: Over the Counter (OTC)

Effect of Supplement: This supplement provides for the implantation of Synovex® C in steers fed in confinement for slaughter when used as part of a reimplant program where Synovex® S is implanted at approximately day 70 after the initial implantation of Synovex® C.

## 2. INDICATIONS FOR USE

**Synovex® C**

Synovex® C is recommended for use in suckling beef calves 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. 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.

## 3. DOSAGE FORM(S), ROUTES(S) OF ADMINISTRATION AND RECOMMENDED DOSAGE

Dosage form: Implantation.

Route of administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.

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.

## 4. EFFECTIVENESS

Effectiveness is established by data in the parent application. Therefore, no further studies were required.

## 5. TARGET ANIMAL SAFETY

Target animal safety is established by data in the parent application. Therefore, no further studies were required.

## 6. HUMAN SAFETY

Human safety is established by data in the parent application. Therefore, no further studies were required.

## 7. AGENCY CONCLUSIONS

Adequate data demonstrates the safe and effective use of Synovex® C and Synovex® S for additional improvement in rate of weight gain when administered to steers fed in confinement for slaughter.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change providing for the implantation of Synovex® C in steers fed in confinement for slaughter when used as part of a reimplant program where Synovex® S is implanted at approximately day 70 after the initial implantation of Synovex® C. 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.

## 8. LABELING

Two (2) pages of labeling are attached as follows:

1. Synovex® S 10 Cartridge Box Label
2. Synovex® C 10 Cartridge Box Label

cc: HFV-199, NADA 9-576 Orig.
HFV-2 (Mailing List)
HFV-12 (FOI Staff)
HFV-102 (GADQC Reserve Copy)
HFV-102 Green Book (NTurner)
HFA-305 (Dockets Management Branch)
HFR-MA350 (District Office Copy)
Sponsor's courtesy copy
ELMonk, HFV-126:5/13/98

ec: CVM Records\\ONADE\\N009576\C0130foi.sum