FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION **NADA 128-409**

NADA SPONSOR:

Merck & Co., Inc.
P.O. Box 2000, WBC-130
Rahway, New Jersey 07065-0914

a. Established Name: Ivermectin

b. Trade/Proprietary Name: Ivomec®

c. Dosage Form: Injectable

d. How Supplied: 200 mL soft, collapsible pack

e. How Dispensed: OTC

f. Amount of Active Ingredient: 2.7 mg/mL (0.27%)

g. Route of Administration: Subcutaneous

h. Species: Grower and Feeder Pigs and Ranch-Raised Foxes

i. Labeled Dosage: Pigs: 300 µg/kg body weight (1 mL/20 lb)
Foxes: 200 µg/kg body weight (.25 mL/6.5 lb), repeat in three weeks.

j. Indications for Use: PIGS: Ivomec Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites:

GASTROINTESTINAL ROUNDWORMS:
Large roundworm, *Ascaris suum* (adults and fourth-stage larvae)
Red stomach worm, *Hyostrongylus rubidus* (adults and fourth stage larvae)
Nodular worm, *Oesophagostomum* spp. (adults and fourth stage larvae)
Threadworm, *Strongyloides ransomi* (adults)

SOMATIC ROUNDWORM LARVAE:

Threadworm, *Strongyloides ransomi* (somatic larvae)
Sows must be treated at least seven days before farrowing to prevent infection in piglets.

LUNGWORMS:
Metastrongylus spp. (adults)

LICE:
Haematopinus suis

MANGE MITES:
Sarcoptes scabiei var. *suis*

RANCH RAISED FOX: For the treatment and control of ear mites (*Otodectes cynotis*).

This FREEDOM OF INFORMATION SUMMARY references data in Public Master File (PMF) 5307, 56 FR 61021, November 29, 1991, in support of the supplemental new animal drug application for ranch-raised foxes. The data were generated by:

William J. Foreyt, Ph.D.
Dept. of Vet. Microbiology and Pathology
Washington State University
Pullman, Washington 99164-7040

2. TARGET ANIMAL SAFETY

Target animal safety data from the FOI summary for PMF 5307, 56 FR 61021, November 29, 1991, demonstrated that based on clinical observation, foxes treated with ivermectin at a dosage of 1000 µg/kg body weight (5X the optimal dose) were not adversely affected by the elevated level of the drug. The data demonstrate that ivermectin injection, when administered subcutaneously at a dosage of 200 µg/kg body weight, twice at a 3 week interval, is safe to ranch-raised foxes.

3. DRUG EFFECTIVENESS:

Efficacy data from the FOI summary for PMF 5307, 56 FR 61021, November 29, 1991, demonstrated that ivermectin injection, when administered subcutaneously at a dose of 200 µg/kg body weight, twice at a 3 week interval, was efficacious in controlling ear mites (*O. cynotis*).

4. AGENCY CONCLUSIONS:

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that ivermectin, when used under the proposed conditions of use, is safe and effective for the control of ear mites (*Otodectes cynotis*) in ranch-raised foxes.

The original approval of ivermectin was as an over-the-counter drug. Accurate diagnosis of ear mites in ranch-raised foxes, which is the new species to be added to the label, can be made with reasonable degree of certainty by the layman. Adequate directions for use have been written for the layman, and the conditions for use prescribed on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall have over-the-counter marketing status.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change. The approval of this change did not require a reevaluation of the safety or effectiveness data in the parent application.