SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY

1. General Information: NADA 12-350.

   a. Sponsor: Merck Sharp & Dohme Research Laboratories
   Division of Merck & Company, Inc.
   P.O. Box 2000
   Rahway, New Jersey 07065

   b. Generic Name: Amprolium.

   c. Trade Name: Amprol (amprolium) 25% Medicated Premix.

   d. Marketing Status: OTC.

2. Indications for Use: For the prevention of coccidiosis in growing pheasants caused by *Eimeria colchici*, *E. duodenalis*, and *E. phasiani*.

3. Dosage Form(s), Route of Administration, and Recommended Dosages:
   Amprolium will be provided as a medicated premix. It is to be fed continuously at a level of 0.0175% in finished pheasant feed as the sole ration.

4. Effectiveness: Please refer to the Freedom of Information Summary under Public Master File (PMF) 3887. Merck referenced these data in support of this NADA supplement. Availability of PMF 3887 was published in the FEDERAL REGISTER of December 24, 1984 (Vol. 49, No. 248) [Docket 84-0412]. The sponsor of this PMF was Interregional Program Number 4 (IR4) Headquarters, Rutgers University, Cook College, New Brunswick, New Jersey 08903.

5. Animal Safety: Please refer to the Freedom of Information Summary under PMF 3887 which Merck has referenced for this approval.

6. Human Safety:

   a. Toxicity Tests and Tolerances: Toxicity studies which were used to establish human safety are described in the FOI summary for NADA 12-350. The toxicity data established tolerances for residues of amprolium of 1 ppm in liver and 0.5 ppm in muscle for chickens and turkeys (21 CFR 556.50). Under the provisions of the agency's minor species regulation (48 FR 1922, January 14, 1983) tolerances of 1 ppm in liver and 0.5 ppm in muscle of pheasants are established for residues of amprolium. On the analysis of the pheasant tissues, it was found that liver contained 0.11 ± 0.07 ppm amprolium, while muscle contained 0.08 ± 0.14 ppm. These values are significantly below the established tolerances and support a zero withdrawal for the use of amprolium in pheasants.

   b. Residue Depletion Study: Refer to FOI Summary of PMF 3887.

7. Agency Conclusions: The agency has concluded that amprolium is not likely to be metabolized differently by pheasants than chickens. Therefore, metabolism data in pheasants are not necessary to support approval of this use of amprolium in pheasants under the provisions of the agency's minor species regulation (48 PR 1920, January 14, 1983).