SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY

I. General Information:

NADA 15-875

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

Generic Name: Thiabendazole

Trade Name: TBZ "200" Medicated Feed Premix

Marketing Status: O.T.C.

II. Indications for Use:

For the treatment of gapeworms (*Syngamus trachea*) in pheasants.

III. Dosage Form(s), Route of Administration, and Recommended Dosages:

Thiabendazole will be provided as a medicated feed premix, i.e., TBZ "200" Medicated Feed Premix. Thiabendazole is administered orally and continuously at a level of 0.05% in complete finished pheasant feed for 2 weeks (14 days).

IV. Effectiveness:

Please refer to the Freedom of Information Summary under Public Master File (PMF) 3857. Merck referenced these data in support of this NADA supplement. PMF 3857 was published in the FEDERAL REGISTER of February 22, 1984 (49 FR 6575). The sponsor of this PMF was IR_4 Headquarters, Rutgers University, Cook College, New Brunswick, New Jersey 08903.

V. Animal Safety:

Please refer to the Freedom of Information Summary under PMF 3857 which Merck has referenced for this approval.

VI. Human Safety:

A. Toxicity Tests and Tolerances

Toxicity studies which were used to establish human safety are described in the FOI summaries under NADA 13-022, NADA 14-350, NADA 48-487, NADA 49-461, NADA 15-123 and NADA 15-875. Authorization to reference the data in these applications was given by Merck, Sharp and Dohme. The toxicity data established a tolerance of 0.1 ppm for residues of thiabendazole in animal derived food (21 CFR 556.730). Under the provisions of the agency's minor species regulation (48 FR 1922, 14 January 1983) a tolerance of 0.1 ppm is established for residues of thiabendazole in the edible tissues of pheasants.

B. Metabolism and Residue Depletion Studies

A residue study was conducted in pheasants involving 4 control birds and 12 medicated birds treated with 0.1% thiabendazole (2X the approved level) in

feed for two weeks. The birds treated with the medicated feed were sacrificed in groups of three at zero, 1, 3, and 4 weeks of withdrawal. Samples of muscle, liver and kidney were collected from the treated and control birds and then assayed by the flourescence analytical method for thiabendazole. A description of the method is filed in the Food Additives Manual on display in FDA's Freedom of Information Public Room (Room 12A-30, 5600 Fishers Lane, Rockville, MD 20857). The method separately determines parent thiabendazole and its 5-hydroxythiabendazole metabolite (both conjugated and unconjugated forms). The results of the assays are shown below expressed as combined thiabendazole and 5-hy-droxythiabendazole.