Approval Date: June 23, 1986

I. GENERAL INFORMATION:

A. NADA 139-488

B. Sponsor: Stutts Scientific Service, Inc.

C. Generic Name: tylosin (as tylosin phosphate)

D. Trade Name: Tylan 5, 10, 20 & 40 Premix

E. Indications For Use

1) **Swine:** For increased rate of weight gain and improved feed efficiency. For prevention of swine dysentery (vibrionic). For maintaining weight gains and feed efficiency in the presence of atrophic rhinitis. For the treatment and control of swine dysentery (vibrionic) following initial medication of Tylan Plus Vitamins in drinking water.
2) **Beef Cattle:** For reduction in the incidence of liver abscesses caused by *Sphaerophorus necrophorus* and *Corynebacterium pyogenes*.
3) **Chickens:** For increased rate of weight gain and improved feed efficiency.
4) **Laying Chickens:** Improving feed efficiency.
5) **Broiler and Replacement Chickens:** To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

F. DOSAGE FORM

Medicated Premix: The premix is to be added to the feed such that the complete feed contains:

1) **Swine:** 10 to 100 grams per ton of tylosin;
2) **Beef Cattle:** 8 to 10 grams per ton of tylosin;
3) **Chickens:** 4 to 50 grams per ton of tylosin;
4) **Broiler Chickens:** 800 to 1000 grams per ton of tylosin;
5) **Replacement Chickens:** 1000 grams per ton of tylosin;
6) **Laying Chickens:** 20 to 50 grams per ton of tylosin.

Feeds containing Tylosin at 800 to 1000 grams per ton must be withdrawn 5 days before chickens are slaughtered.

II. SUMMARY OF SAFETY AND EFFECTIVENESS DATA

The safety and efficacy data upon which this application was approved are found in NADA 12-491 for Elanco Products Company and are summarized in an FOI Summary in Docket Number 75N-0065.

III. AGENCY CONCLUSION

Approval of this application is based on safety and effectiveness data contained in Elanco Products Company's approved NADA 012-491. Use of the data in NADA 012-491 to support this application has been authorized by Elanco. This approval does not change the approved use of the drug. Consequently, approval of this NADA poses no increased human risk from exposure to residues of the animal drug, nor does it change the conditions of the drug's safe use in the target animal species. Accordingly, under the Center for Veterinary Medicine's supplemental approval policy (42 FR 64367), this is equivalent to a Category II supplemental approval which does not require reevaluation of the safety and effectiveness data in the original approval.

IV. LABELING (Attached)

1) Tylan 40 product label.
2) Tylan 20 product label.
3) Tylan 10 product label.
4) Tylan 5 product label.

Copies of these labels may be obtained by writing to the:
Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.