Approval Date: June 6, 2002

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-863

Ractopamine hydrochloride (PAYLEAN®)

For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

Sponsored by:

Elanco Animal Health
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

FREEDOM OF INFORMATION SUMMARY

Purpose of supplement: To amend cautionary language in product labeling

I. GENERAL INFORMATION:

NADA Number: 140-863

Sponsor: Elanco Animal Health
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Generic Name: Ractopamine hydrochloride

Trade Name: Paylean®

Marketing Status: Over the Counter (OTC)

II. INDICATIONS FOR USE:

For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

III. DOSAGE:

a. Dosage Form: Paylean® Type A Medicated Article is available as a 25-pound bag containing 9 or 45 grams of ractopamine hydrochloride per pound.

b. Route of Administration: Oral, via the feed

c. Recommended Dosage:

Ractopamine hydrochloride should be fed at a concentration of 4.5 g of ractopamine hydrochloride per ton of complete feed (5 ppm) for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in a ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

Ractopamine hydrochloride should be fed at a concentration of 4.5 g to 18 g of ractopamine hydrochloride per ton of complete feed (5 ppm to 20 ppm) for improved feed efficiency and increased carcass leanness in a ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

IV. EFFECTIVENESS:

No re-evaluation of the effectiveness was necessary to support this approval.

V. ANIMAL SAFETY:

A. Monitoring of adverse event information reported subsequent to product marketing

The Center for Veterinary Medicine requested that Elanco submit a supplemental NADA to revise the Paylean label to improve product safety and ensure that the most current information is available to producers. The request was made in response to an increase in downer pigs in slaughter plants subsequent to the approval of Paylean. The need for a label change was prompted by adverse event reports submitted to the center by Elanco, reports from USDA FSIS, and an Elanco-sponsored post-approval study.

The Paylean label change was approved June 1, 2001. The original label was modified by adding the following caution statement: "Caution: Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean."

VI. HUMAN SAFETY:

No re-evaluation of the human safety data was necessary to support this approval.

VII. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations demonstrate that use of ractopamine hydrochloride at a concentration of 4.5 to 18 g/ton (5 ppm to 20 ppm) with the approved additional caution statement is safe and effective for the claims indicated in section II of this FOI Summary.

Pursuant to 21 CFR 514.106(b)(2), this supplemental NADA approval is regarded as a Category II supplemental change which did not require a reevaluation of safety and efficacy data in the parent NADAs. The drug is to be fed in Type C medicated feeds, in accordance with section II and III of the FOI Summary.

Attachments:

Type A Medicated Article Label (Paylean® 45)
Type C Medicated Feed Label (Bluebird with Caution Addition)

Net Weight lb (kg) on bag or bulk

Paylean® Finishing Swine Feed

Type C Medicated Feed

For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

ACTIVE DRUG INGREDIENT

Ractopamine hydrochloride..... 4.5 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than..... 16.00 %
Lysine, not less than..... _____%
Crude Fat, not less than..... _____%
Crude Fiber, not more than..... _____%
Calcium, not less than..... _____%
Calcium, not more than..... _____%
Phosphorus, not less than..... _____%
Salt[1], not less than..... _____%
Salt[1], not more than..... _____%
Sodium[2], not less than..... _____%
Sodium[2], not more than..... _____%
Selenium, not less than..... _____ppm
Zinc, not less than..... _____ppm

[1]If added.
[2]Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

DIRECTIONS FOR USE

Feed continuously to finishing swine as the sole ration from 150 lb (68 kg) to 240 lb (109 kg) body weight.

WARNING: The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Not for use in humans. Keep out of the reach of children. The Paylean formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Paylean, use protective clothing, impervious gloves, protective eye wear, and a NIOSH-approved dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse eyes thoroughly with water. If irritation persists, seek medical attention. The material safety data sheet contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

CAUTION: Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean. Not for use in breeding swine.

MANUFACTURED BY

BLUE BIRD FEED MILL
Any town, USA 12345

Paylean® is a registered trademark of Eli Lilly and Company.

Net Weight lb (kg) on bag or bulk

Paylean® Finishing Swine Feed

Type C Medicated Feed

For improved feed efficiency and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

ACTIVE DRUG INGREDIENT

Ractopamine hydrochloride..... 4.5 to 18 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than	16.00 %
Lysine, not less than	_____%
Crude Fat, not less than	_____%
Crude Fiber, not more than	_____%
Calcium, not less than	_____%
Calcium, not more than	_____%
Phosphorus, not less than	_____%
Salt[1], not less than	_____%
Salt[1], not more than	_____%
Sodium[2], not less than	_____%
Sodium[2], not more than	_____%
Selenium, not less than	_____ppm
Zinc, not less than	_____ppm

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