Date of Approval: July 18, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-548

ACTOGAIN 45

ractopamine hydrochloride

Type A medicated article for use in the manufacture of Type B or Type C medicated feeds

Cattle fed in confinement for slaughter

Complete Feed:
(8.2 – 24.6 g/ton) - For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.
(9.8 – 24.6 g/ton) - For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Top Dress Feed:
(70-400 mg/head/day) – For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Sponsored by:

Zoetis Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-548

B. Sponsor

Zoetis Inc.
333 Portage St.
Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Name

ACTOGAIN 45

D. Established Name

ractopamine hydrochloride

E. Pharmacological Category

Beta-adrenergic agonist

F. Dosage Form

Type A medicated article for use in the manufacture of Type B (liquid or dry) and Type C medicated feeds

G. Amount of Active Ingredient

45.4 g/lb

H. How Supplied

25 lb bag (11.34 kg)

I. Dispensing Status

OTC

J. Dosage Regimen

Complete feed use:
Ractopamine hydrochloride Type C medicated feed is fed continuously as a sole ration at a dietary concentration of 8.2 to 24.6 g of ractopamine hydrochloride per ton of feed for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.

Ractopamine hydrochloride Type C medicated feed is fed continuously as a sole ration at a dietary concentration of 9.8 to 24.6 g of ractopamine hydrochloride per ton of feed for increased rate of weight gain, improved feed efficiency and

increased carcass leanness in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.

Top dress feed use:
Ractopamine hydrochloride is fed at 70 to 400 mg/head/day, as provided in a minimum of 1.0 lb of top dressed Type C medicated feed containing a maximum of 800 g/ton ractopamine for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. Note: Carcass leanness effects are not an approved indication for use when feeding ractopamine by top dress feeding methods.

K. Route of Administration

Oral, in feed

L. Species/Class

Cattle fed in confinement for slaughter

M. Indicactions

Complete Feed:
(8.2 – 24.6 g/ton) - For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter the last 28 to 42 days on feed.

(9.8 – 24.6 g/ton) - For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

Top Dress Feed:
(70-400 mg/head/day) – For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 28 to 42 days on feed.

N. Reference Listed New Animal Drug

OPTAFLEXX 45; ractopamine hydrochloride; NADA 141-221; Elanco Animal Health, A Division of Eli Lilly & Co.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the

generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on meeting the criteria for the dosage adjusted solubility requirements for swine and cattle as described in Guidance for Industry #171, "Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles", Zoetis Inc. was granted a waiver from the requirement to demonstrate bioequivalence for their generic product, ACTOGAIN 45 (ractopamine hydrochloride) Type A medicated article. This generic product contains the same active ingredient in the same concentration as the RLNAD. The generic and the RLNAD Type C medicated feeds are fed as complete or top dress feeds that are manufactured from the Type A medicated article or Type B (liquid or dry) medicated feed.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

The product labeling contains the following information regarding safety to cattle fed ractopamine hydrochloride:

CAUTION: Not for animals intended for breeding

V. HUMAN FOOD SAFETY:

The following are assigned to this product for cattle:

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product. A tolerance for ractopamine hydrochloride (the marker residue) in cattle is 0.03 part per million (ppm) in muscle and 0.09 (ppm) in liver, under 21 CFR 556.570(b)(1). The acceptable daily intake (ADI) for total residues of ractopamine hydrochloride is 1.25 micrograms per kilogram of body weight per day.

B. Withdrawal Times:

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal times are those previously assigned to the RLNAD product.

A withdrawal period of zero days has been established for ractopamine hydrochloride in cattle.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of ractopamine hydrochloride is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to ACTOGAIN 45:

NOT FOR HUMAN USE

WARNING: The active ingredient in Actogain, 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 Actogain 45 formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Actogain, 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 product information, call 1-888-963-8471.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that ACTOGAIN 45, when used according to the label, is safe and effective.