Date of Approval: October 1, 2021

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-691

RAC™ 45 CATTLE

(ractopamine hydrochloride Type A medicated article)

Type A medicated article to be used in manufacture of Type B and Type C medicated feeds

Cattle fed in confinement for slaughter

Complete Feed: 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: 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.

Sponsored by:

Virbac AH, Inc.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-691

B. Sponsor

Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Drug Labeler Code: 051311

C. Proprietary Name

RAC™ 45 CATTLE

D. Drug Product Established Name

ractopamine hydrochloride Type A medicated article

E. Pharmacological Category

Beta-adrenergic agonist

F. Dosage Form

Type A medicated article to be used in the manufacture of Type B and Type C medicated feeds

G. Amount of Active Ingredient

45.4 g per lb (100 g per kg)

H. How Supplied

25 lb (11.34 kg) bag

I. Dispensing Status

Over-the-counter (OTC)

J. Dosage Regimen

Complete Feed

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed[a]	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain, and Improved Feed Efficiency	8.2 to 24.6 g/ton (9 ppm to 27 ppm)	70-430
Increased Rate of Weight Gain, Improved Feed Efficiency, and Increased Carcass Leanness	9.8 to 24.6 g/ton (11 ppm to 27 ppm)	90-430

[a]Based on 90% Dry Matter Basis

Directions for use (Complete Feed): Feed continuously to cattle fed in confinement for slaughter as the sole ration for the last 28 to 42 days on feed.

Top Dress Feed:

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed[a]	Ractopamine (mg/hd/d)
Increased Rate of Weight Gain and Improved Feed Efficiency	Appropriate Concentration of Ractopamine in a minimum of 1.0 lb **Top Dressed** Type C Medicated Feed[a] (maximum of 800 g/ton)	70-400

[a]Based on 90% Dry Matter Basis

Directions for Use (Type C Medicated Top Dress Feed): Feed continuously to cattle fed in confinement for slaughter a Type C Medicated Feed containing up to a maximum of 800 g/ton ractopamine (see mixing directions table) to provide 70 to 400 mg/head/day for the last 28 to 42 days on feed. Type C Medicated Top Dress feed must be fed in a minimum of 1.0 lb per head per day to provide 70 to 400 mg/head/day.

K. Route of Administration

Oral

L. Species/Class

Cattle fed in confinement for slaughter

M. Indications

Complete Feed: 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: 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.

N. Reference Listed New Animal Drug (RLNAD)

Optaflexx™ 45; ractopamine hydrochloride Type A medicated article; NADA 141-221; Elanco US Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Virbac AH, Inc., was granted a biowaiver for the generic product RAC™ 45 CATTLE (ractopamine hydrochloride Type A medicated article) to be used in the manufacture of Type B and Type C medicated feeds. The generic drug product is a Type A medicated article, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Optaflexx™ 45 (ractopamine hydrochloride Type A medicated article) to be used in the manufacture of Type B and Type C medicated feeds, sponsored by Elanco US Inc., under NADA 141-221, and was approved for use in cattle fed in confinement for slaughter on June 13, 2003.

III. HUMAN FOOD SAFETY

The tolerance for residues and withdrawal period established for the RLNAD apply to the generic product. The following are assigned to this product for cattle fed in confinement for slaughter:

A. Acceptable Daily Intake and Tolerances for Residues

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

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of zero days has been established for ractopamine hydrochloride Type A medicated article in cattle fed in confinement for slaughter.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of ractopamine hydrochloride is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

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

NOT FOR HUMAN USE

WARNING: The active ingredient in RAC™ 45 CATTLE, 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 RAC™ 45 CATTLE formulation (Type A medicated article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling RAC™ 45 CATTLE, 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 safety data sheet contains more detailed occupational safety information.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that RAC™ 45 CATTLE, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from cattle fed in confinement for slaughter treated with RAC™ 45 CATTLE will not represent a public health concern when the product is used according to the label.