- Unpublished study T4V-LC-ERAA from Pharmaco LSR, 706 Banister Lane, Austin, Texas 78704, USA.
- 17. Dalidowicz JE, Thomson TD & Herberg RJ (1985); ¹⁴C-EL-737 Steady-State Residue Study with Swine Fed the Highest Anticipated Dose.
 - Unpublished study ABC-0273 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- Dalidowicz JE, Thomson TD & Herberg RJ (1985); ¹⁴C EL-737 Tissue Depletion Study in Swine.
 Unpublished study ABC-0291 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company,
 Greenfield, IN, USA.
- Dalidowicz JE, Lewis JJ & Thomson TD (1986); ¹⁴C-Ractopamine HCl Swine Tissue Residue Study.
 Unpublished study ABC-0368 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company,
 Greenfield, IN, USA.
- Donoho AL, Macy TD & Cochrane RL (1991) ; Ractopamine Tissue Residue Decline Study in Swine.
 Unpublished Report T4V759003 from Animal Science Chemical Research, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- Dalidowicz JE & Thomson TD (1988); ¹⁴C-Ractopamine HCl Tissue Residue Steady-State Study in Cattle.
 Unpublished study ABC-0398 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company,
 Greenfield, IN, USA.
- 22. Dalidowicz JE, Lewis JJ, Thomson TD & Herberg RJ (1987); ¹⁴C Ractopamine HCl Tissue Depletion Study in Cattle. Unpublished study ABC-0375 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 23. Smith DJ & Shelver WL (2002); Tissue Residues of Ractopamine and Urinary Excretion of Ractopamine and Metabolites in Animals Treated for 7 days With Dietary Ractopamine.
 - J. Anim. Sci. : 2002 (80), 1240-1249.
- 24. Dalidowicz JE (1989) ; Comparative Metabolism of ¹⁴C-Ractopamine HCl in Cattle, Dogs, and Rats.

 Unpublished study ABC-0387 from Animal Science Chemical Research, Lilly Research laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 25. Dalidowicz JE (1987) ; Comparative Metabolism of ¹⁴C -Ractopamine HCl in Swine, Dogs and Rats.
 Unpublished study ABC-0369 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company,
 Greenfield, IN, USA.
- 26. Dalidowicz JE (1985) ; ¹⁴C Ractopamine HCl "Nonextractable" Residues in Swine Liver and Kidneys.
 Unpublished data related to study ABC-0291 from Agricultural Biochemistry, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 27. Smith DJ, Giddings JM, Heil VJ & Paulson GD (1995) ; Identification of Ractopamine Hydrochloride Metabolites Excreted in Rat Bile.
 - Xenobiotica.: 1995(25), No. 5, 511-520.
- Smith DJ & Rodewald JM (1994); Urinary Excretion of Ractopamine and its Conjugated Metabolites by Humans.
 Unpublished study T4V759404 from Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 29. Williams GD, McKinley ER & Bridge TL (1985a). ; The acute toxicity of compound 31537 (EL-737) administered orally to the ICR mouse.
 - Unpublished Reports M-0-179-84 and M-0-178-84 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.

- 30. Williams GD, McKinley ER & Bridge TL (1985b) : The acute toxicity of compound 31537 (EL-737) administered orally to the Fischer 344 rat.
 - Unpublished Report R-0-133-84 and R-0-132-84 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 31. Williams GD, McKinley ER & Bridge TL (1985c) ; The acute toxicity of compound 31537 (EL-737) administered intraperitoneally to the Fischer 344 rat.
 - Unpublished Reports R-P-08-84 and R-P-09-84 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 32. Williams GD, Negilski DS & Markey TF (1984b) ; The acute dermal, ocular, and inhalation toxicity of compound 31537 (EL-737). Unpublished Reports B-D-82-84, B-E-108-84 and R-H-47-84 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 33. Williams GD, Negilski DS, Bridge TL & Markey TF (1985f) ; The acute oral, dermal, ocular and inhalation toxicity of a granular premix formulation (AFN-026) containing 10% compound 31537 (EL-737).
 Unpublished Reports R-0-188-85, B-D-104-85, B-E-120-85, and R-H-066-85 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 34. Williams GD (1987b); A Three-Month Toxicity Study of Ractopamine Hydrochloride Fed in the Diet to B6C3F1 Mice. Unpublished study M01584 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 35. Williams GD (1984) ; A Three-Month Subchronic Toxicity Evaluation of 031537 (Ractopamine Hydrochloride) Administered Orally to Fischer 344 Rats.
 - Unpublished study R06184 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 36. Williams GD & Shoufler JR (1993) ; A Subchronic Toxicity Study of Ractopamine Hydrochloride Given by Nasogastric Gavage to Rhesus Monkeys for 6 Weeks.
 - Unpublished study P00691 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 37. Williams GD & Stone DN (1987a); Special Study: The Effect of Subchronic Administration of Ractopamine Hydrochloride on Heart Rate and Electrocardiographic Waveforms in Conscious Rhesus Monkeys.
 - Unpublished study P02186 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA. .
- 38. Williams GD, McKinley ER & Bridge TL (1985d). ; 18-Day inhalation study in rhesus monkey.

 Unpublished Report P00388 from Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, Indiana, USA.
- 39. Williams GD, Carlson KH & Wolff RK (1989) ; A subchronic inhalation study of ractopamine hydrochloride in rhesus monkeys. Unpublished Report P06288 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 40. Williams GD (1987d); A Target Animal Safety and Drug Tolerance Study of Ractopamine Hydrochloride Administered in the Diet of Swine During the Finishing Period.
 - Unpublished study T4VVX8510 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 41. Williams GD (1987c); A Chronic Toxicity Study of Ractopamine Hydrochloride Administered Orally to Beagle Dogs for One Year.

 Unpublished study D05885 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield,

IN, USA.

42. Williams GD (1998a); An Oncogenic Study and Companion Blood Level Study in CD-1 Mice Given Ractopamine Hydrochloride in the Diet for 21 Months.

Unpublished study M04196, M04296 & M04396 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.

43. Gibson JP, Sells DM, Cheng HC & Yuh L (1987) Induction of uterine leiomyomas in mice by medroxalol and prevention by propranolol.

Toxicol. Pathol. : 1987(15), No.4, 468-473.

44. Gopinath C & Gibson WA (1987) Mesovarian leiomyomas in the rat.

Environ. Health Persp. : 1987(73),107-113.

45. Jack D, Poynter D & Spurling NW (1983) Beta-adrenoreceptor stimulants and mesovarian leiomyomas in the rat.

Toxicology: 1983(27), 315-320.

- 46. Williams GD (1998b) An Oncogenic Study in Fischer 344 Rats Given Ractopamine Hydrochloride in the Diet for 2 Years. Unpublished study R16696 & R16796 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 47. Williams GD (1993); A Chronic Study to Evaluate the Toxicity of Ractopamine HCl in a Nonrodent Species Whose Cardiovascular Responsiveness Approximates That of Humans Given This Class of Compounds.

Unpublished study P05191 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.

- 48. Williams GD & Hoyt JA (1987) ; An Eleven-Month Two-Generation Reproduction Study, Including a Teratology Segment, in CD Rats Maintained on Diets Containing Ractopamine Hydrochloride (EL-737, Compound 31537).
 - Unpublished studies R11385 and R18985 from Toxicology Division, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 49. Williams GD (1989); A Reproductive Safety Study in Pigs (Gilts) Administered Ractopamine Hydrochloride in the Diet During the Finishing Period.
 - Unpublished study VX8713 from Toxicology Division, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 50. Williams GD, Hill LE & Probst GS (1984a); The effect of compound 31537, EL-737, on the induction of DNA repair synthesis in primary cultures of adult rat hepatocytes.
 - Unpublished Reports 840503UDS2000 and 840508UDS2000 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 51. Williams GD, Rexroat MA & Probst GS (1984d) ; The effects of EL-737 (compound 31537) on the induction of reverse mutations in Salmonella typhimurium using the Arnes test.
 - Unpublished Report 840716AMS2000 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 52. Williams GD & Thompson CZ (1984); The effect of compound 31537, EL-737 on the induction of bacterial mutation using a modification of the Ames test.
 - Unpublished Report 840507GPA2000 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 53. Garriott ML & Rexroat MA (1996) ; The Effect of Ractopamine Hydrochloride on the Induction of Reverse Mutations in Salmonella typhimurium and Escherichia coli Using the Ames Test.

- Unpublished studies 951114AMS2000 and 951205AMS2000 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 54. Akhurst LC (1995) ; Ractopamine Hydrochloride Metaphase Chromosome Analysis of Human Lymphocytes Cultured In Vitro. Unpublished study DTA 5/941656 from Huntington Research Centre, Ltd., Huntington, Cambridgeshire, PE 18 6ES, England.
- 55. Murli H (1996a); Mutagenicity Test On Ractopamine Hydrochloride Measuring Chromosomal Aberrations in Human Whole Blood Lymphocytes With and Without Exogenous Metabolic Activation.
 - Unpublished study 17282-0-449EC from Corning Hazleton Inc. (CHV), 9200 Leesburg Pike, Vienna, VA 22182, USA.
- 56. Jackson MS & Garriott ML (1996); The Effect of Ractopamine Hydrochloride on the In Vitro Induction of Chromosome Aberrations in Chinese Hamster Ovary Cells.
 - Unpublished studies 951108CAB2000 and 951206CAB2000 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 57. Williams GD, Oberly TJ, Bewsey, BJ & Probst GS (1984c); The effect of 31537 (EL-737) on the induction of forward mutation at the thymidine kinase locus of L517Y mouse lymphoma cells.
 - Unpublished Report 840627MLA2000 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 58. Garriott ML & Yount DJ (1996) ; The Effect of Ractopamine Hydrochloride On The Induction of Forward Mutation At The Thymidine Kinase Locus OF L5178Y Mouse Lymphoma Cells.

 Unpublished studies 951115MLA2000 and 951219MLA2000 from Toxicology Research Laboratories, Lilly Research Laboratories,

A Division of Eli Lilly and Company, Greenfield, IN, USA.

- 59. Cifone MA (1996); Mutagenicity Test On Ractopamine Hydrochloride In The L5178Y TK+/- Mouse Lymphoma Forward Mutation Assay.
 - Unpublished study 17282-0-431 from Corning Hazleton Inc. (CHV), 9200 Leesburg Pike, Vienna, VA 22182, USA.
- 60. Murli H (1996b); Mutagenicity Test On Ractopamine Hydrochloride (compound 031537) Measuring Chromosomal Aberrations In Vivo In Mouse Bone Marrow Cells.
 - Unpublished study 17282-0-451 from Corning Hazleton Inc. (CHV), 9200 Leesburg Pike, Vienna, VA 22182, USA.
- 61. Murli H (1996c) ; Mutagenicity Test On Ractopamine Hydrochloride (compound 031537) Measuring Chromosomal Aberrations In Vivo In Mouse Bone Marrow Cells.
 - Unpublished study 17282-2-451 from Coming Hazleton Inc. (CHV), 9200 Leesburg Pike, Vienna, VA 22182, USA.
- 62. Garriott ML, Schwier LS, Parton JW & Williams GD (1993); The Effect of Ractopamine Hydrochloride Given Orally for 2 Consecutive Days on the Induction of Micronuclei in Bone Marrow of ICR Mice.
 - Unpublished study 930811MNT2000 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 63. Garriott ML, Schwier LS & Parton JW (1996) ; The Effect of Ractopamine Hydrochloride Given Orally by Gavage for 14 Consecutive Days On The Induction of Micronuclei in Bone Marrow of Fischer 344 Rats.
 - Unpublished studies 960610MNT2000 and 960815MNT2000 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 64. Williams GD, Neal SB & Probst GS (1985e) ; The effect of compound 31537 (EL-737) on the *in vivo* induction of sister chromatid exchange in bone marrow of Chinese hamsters.
 - Unpublished Report 850121SCE2000 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 65. Murphy AT & Gillespie TA (1996) ; Analysis of Mouse Lymphoma Cell Culture Media for Ractopamine and Ractopamine

- Catechol using LC/MS/MS.
- Unpublished summary document from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Indianapolis, IN, USA.
- 66. Oberly TJ & Yount DJ (1996) ; Effect of Ractopamine Hydrochloride on the Induction of Forward Mutation at the Thymidine Kinase Locus of L5178Y Mouse Lymphoma Cells:
 - Unpublished special studies 960313MLA2000, 960409MLA2000, 960416MLA2000, 960423MLA2000, 960723MLA2000. 960730MLA2000, 961015MLA2000, & 961030MLA2000 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 67. Williams GD & Stone DN (1987b); Special Study: The Hemodynamic Effects of Intravenous Administration of Ractopamine Hydrochloride in Anesthetized Dogs.

 Unpublished study DC1485 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield,

IN, USA.

- Sarazan RD, Main BW & Williams, GD (1993); An Acute Cardiovascular Toxicity Study with Ractopamine HCl (Compound 031537) Administered Orally in the Conscious Instrumented Beagle.
 - Unpublished study DV0193 from Toxicology Research Laboratories, Lilly Research Laboratories, A Division of Eli Lilly and Company, Greenfield, IN, USA.
- 69. Williams GD & Stone DN (1987c); Special Study: The Hemodynamic Effects of Intravenous Administration of Ractopamine Hydrochloride in Anesthetized Monkeys.
 - Unpublished study P07585 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 70. Williams GD & Stone DN (1987d); Special Study: The Effects of Intravenous Administration of Ractoparnine Hydrochloride Compared in Conscious and Anesthetized Monkeys.
 - Unpublished study P07685 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 71. Williams GD, Grothe DW & Francis PC (1986d); The Acute Toxicity of Ractopamine Hydrochloride (EL-737, Compound 31537) to Rainbow Trout (Salmo gairdneri) in a Static Test System.
 - Unpublished study F03286 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 72. Williams GD, Grothe DW & Francis PC (1986e); The Acute Toxicity of Ractopamine Hydrochloride (EL-737, Compound 31537) to Bluegill (*Lepomis macrochirus*) in a Static Test System.
 - Unpublished study F03186 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 73. Williams GD, Grothe DW & Francis PC (1986f); The Acute Toxicity of Ractopamine Hydrochloride (EL-737, Compound 31537) to <u>Daphnia magna</u> in a Static Test System.
 - Unpublished study C00786 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 74. Williams GD, Cochrane RL & Meyerhoff RD (1986a); The Toxicity of Ractopamine Hydrochloride (EL-737, Compound 31537) to Juvenile Mallards in a Five-Day Dietary Study.
 - Unpublished study A00986 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 75. Williams GD, Cochrane RL & Meyerhoff RD (1986b) ; The Toxicity of Ractopamine Hydrochloride (EL-737, Compound 31537)

- to Bobwhite in a 14-Day Acute Oral Study.
- Unpublished study A00586 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 76. Williams GD, Cochrane RL & Meyerhoff RD (1986c) : The Toxicity of Ractoparnine Hydrochloride (EL-737, Compound 31537) to Juvenile Bobwhite in a Five-Day Dietary Study.
 Unpublished study A01186 from Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- 77. Mercier O (1992); Test To Evaluate Sensitizing Potential In The Guinea-Pig.
 Unpublished study 207309 from Hazleton France, Les Oncins, B.P. 0118, 69593 L'Arbresle Cedex, France.
- 78. Lewis JJ (1985); Antimicrobial activity of ractopamine hydrochloride.

 Unpublished study JJL8505 from Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN, USA.
- Sears MR (2002); Adverse effects of β-agonists;
 J. Allergy Clin Immunol: 2002 (110), No.6, 322-328
- 80. The 2004 Prohibited List International Standard; World anti-doping agency Update 17 March 2004
- 81. CANTOX; Responses to commentary regarding Ractopamine hydrochloride by the Joint Expert Committee on Food Additives, August, 2000 (Unpublished)
- 82. Public Release Summary on Evaluation of the new active RACTOPAMINE HYDROCLORIDE; Australian Pesticides and Veterinary Medicines Authority (July 2003)
- 83. VICH GL32; Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing
- 84. Hurtt ME, Cappon GD, Browning A (2003); Proposal for a tiered approach to developmental toxicity testing for veterinary pharmaceutical products for food-producing animals.

Food Chem Toxicol.: 2003 (41), No.5, 611-619

85. WHO TRS 799 (1990)