Public Master File 006555 (submission A-0000)

PMF006555_Drouillard_2025_Project summary

Memorandum to File: Study 1U01FD006804-01

Center for
Veterinary Medicine

P-006555-A-0000-OT (AA)
(tylosin phosphate Type A medicated article)
Beef Cattle
January 12, 2024

MEMORANDUM TO FILE

On September 29, 2023, CVM created a public master file (PMF) 006555 to include studies (reports and data) associated with defining a duration of use for tylosin phosphate Type A medicated article for reduction of the incidence of liver abscesses in beef cattle.

FDA/CVM awarded Dr. James Drouillard [Kansas State University, KSU; Principal Investigator (PI)] a grant through Funding Opportunity Announcement (FOA) number RFA-FD-19-024 (https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-19-024.html) titled, "Conduct Studies to Establish More Targeted Durations of Use for Certain Approved Antimicrobial New Animal Drugs in Food Animals." The award project number was 1U01FD006804-01 (https://reporter.nih.gov/project-details/9942089). This study was intended to generate publicly available data that may be used to help define the duration of use for tylosin phosphate to reduce the incidence of liver abscesses in beef cattle, in support of revisions to the conditions of use for tylosin-containing medicated feeds, which are currently approved without a defined duration of use for this indication. As outlined in CVM's draft Guidance for Industry #273, Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals (published for public comment in September 2023), CVM encouraged sponsors to voluntarily establish defined durations of use for indications that lack them.

Data for Study 1U01FD006804-01 was submitted to CVM by the investigator (Drouillard) on January 17, 2023, and will be filed with this submission. Public disclosure was granted for data and reports associated with Study 1U01FD006804-01 on January 17, 2023.

Documents in this submission (see Appendix):

- Final study report, data, and other study related files submitted by the investigator for Study 1U01FD006804-01
- CVM-prepared summary of Study 1U01FD006804-01

  The results of Study 1U01FD006804-01 were not conclusive, but suggest that 60 mg tylosin/head/day administered only for the first 30 or 60 days on transition and finishing feedlot rations may not be effective in reducing the incidence of liver abscesses in Angus-type steers.

  Limitations of this study prohibit drawing any definitive conclusions. Tylosin assay results for the Type C medicated feeds fed during this study could not be used to confirm dosing, in part because the (b) (4) method (b) (4) is not validated at the lower inclusion rates necessary for use in this study; therefore, the reported assay results may not be reliable. Additionally, this single-site study using only Angus-type steers is insufficient to evaluate repeatability of the study results, particularly across different cattle breeds and different geographic locations.

The information and observations from this study, along with other available information, may be useful in helping veterinarians decide when and how long to administer tylosin for this indication, or in developing future studies to further evaluate and optimize the timing and duration of use.

{see appended electronic signature page}
Charlotte Hatch, DVM
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Antimicrobial Drugs Team, HFV-133
Office of New Animal Drug Evaluation

Appendix

Appendix. Review related files in this submission:

CDMS File Name:	Contents:
P-006555-A-0000-OT-AA_data.xml	1U01FD006804-01 data.xml (study data)
P-006555-A-0000-OT-AA _orrf.pdf	1U01FD006804-10 Final Research Performance Progress Report (final study report and copies of the raw data)
P-006555-A-0000-OT-AA _orrf_2.pdf	1U01FD006804-10 FRPPR Table of Contents (table of contents for the final study report)
P-006555-A-0000-OT-AA_orrf_3.pdf	CARCASS_ANALYSIS_RESULTS
P-006555-A-0000-OT-AA_orrf_4.pdf	CARCASS_ANALYSIS_SASOUTPUT
P-006555-A-0000-OT-A_orrf_5.pdf	CARCASS_SUMMARY_STATISTICS_AND_PLOTS
P-006555-A-0000-OT-AA_orrf_6.pdf	PERFORMANCE_ANALYSIS_RESULTS
P-006555-A-0000-OT-AA_orrf_7.pdf	PERFORMANCE_ANALYSIS_SASOUTPUT
P-006555-A-0000-OT-AA_orrf_8.pdf	PERFORMANCE_SUMMARY_STATISTICS_AND_PLOTS
P-006555-A-0000-OT-AA_orrf_10.pdf	CVM-prepared summary of Study 1U01FD006804-01

Document Sign-Off Addendum

Submission Details			
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