ALEI AGRICULTURE AND ENVIRONMENTAL LAW
CONFERENCE
“ADMINISTERING ANTIBIOTICS TO LIVESTOCK IN MARYLAND”
“THE LEGAL FRAMEWORK”
ANNAPOLIS, MARYLAND
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1996-National Antimicrobial Resistance Monitoring System (NARMS) is established.

2003-Guidance for Industry #152 –FDA drug approvals are based on risk assessment for antimicrobial resistance.

2010-Guidance for Industry #209-FDA established judicious use practices of medically important antimicrobials.

2013-Guidance for Industry #213-FDA established the three year time line to convert OTC status to VFD for medicated feed products and Rx for medicated drinking water products.

January 1, 2017-21 CFR Part 558 requires all medically important antimicrobials to be dispensed as a VFD or Rx drug order.
KEY POINTS FOR VFD AND RX USAGE OF MEDICALLY IMPORTANT ANTIMICROBIALS
A legal VFD and RX antimicrobial drug order relies on these three entities

Veterinarian

Producer

Distributor
A Veterinarian-Client-Patient Relationship (VCPR) exists when:

- RESPONSIBILITY ESTABLISHED
- SUFFICIENT KNOWLEDGE AND TIMELY VISITS
- AVAILABILITY

A VALID VCPR WITH A MARYLAND LICENSED VETERINARIAN

COMAR Title 15, Department of Agriculture, Subtitle 14 Board of Veterinary Medical Examiners, Chapter 1; Standards of Practice and Code of Ethics for the Practice of Veterinary Medicine in the State (COMAR 15.14.01.01)
DISTRIBUTORS MUST NOTIFY FDA CVM

ONE TIME NOTIFICATION

- As of December, 2015: 4 Maryland Distributors had notified FDA CVM
- As of August, 2016: 30 Maryland Distributors have notified FDA CVM
- As of December 31, 2016: 59 Maryland Distributors have notified FDA CVM
PRODUCER REQUIREMENTS

- Producer must obtain a VFD or Rx order from their veterinarian for medically important antimicrobials.
- A extralabel use of a medically important antimicrobial is not allowed.
- No refills are allowed.
- No usage after the expiration date is allowed.
- Maintain a copy of the VFD for 2 years.
- Maintain a copy of the Rx for 5 years - MD pharmacy laws and regulations.
REFERENCES

- FDA Center for Veterinary Medicine VFD website: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
Keep Antibiotics Effective Act of 2017 became a law on October 1, 2017.

On December 1, 2019, the Maryland Department of Agriculture shall report to the General Assembly Maryland usage of medically important antimicrobials.

This law does not apply for reporting antimicrobial usage:
- for a cattle operation that sells fewer than 200 cattle per year
- for a swine operation that sells fewer than 200 swine per year
- for a poultry operation that sells fewer than 60,000 birds per year

A working group has been established in Animal Health to carry out this law.
THANK YOU

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