

ALEI AGRICULTURE AND ENVIRONMENTAL LAW CONFERENCE

“ADMINISTERING ANTIBIOTICS TO LIVESTOCK IN MARYLAND” “THE LEGAL FRAMEWORK”

ANNAPOLIS, MARYLAND

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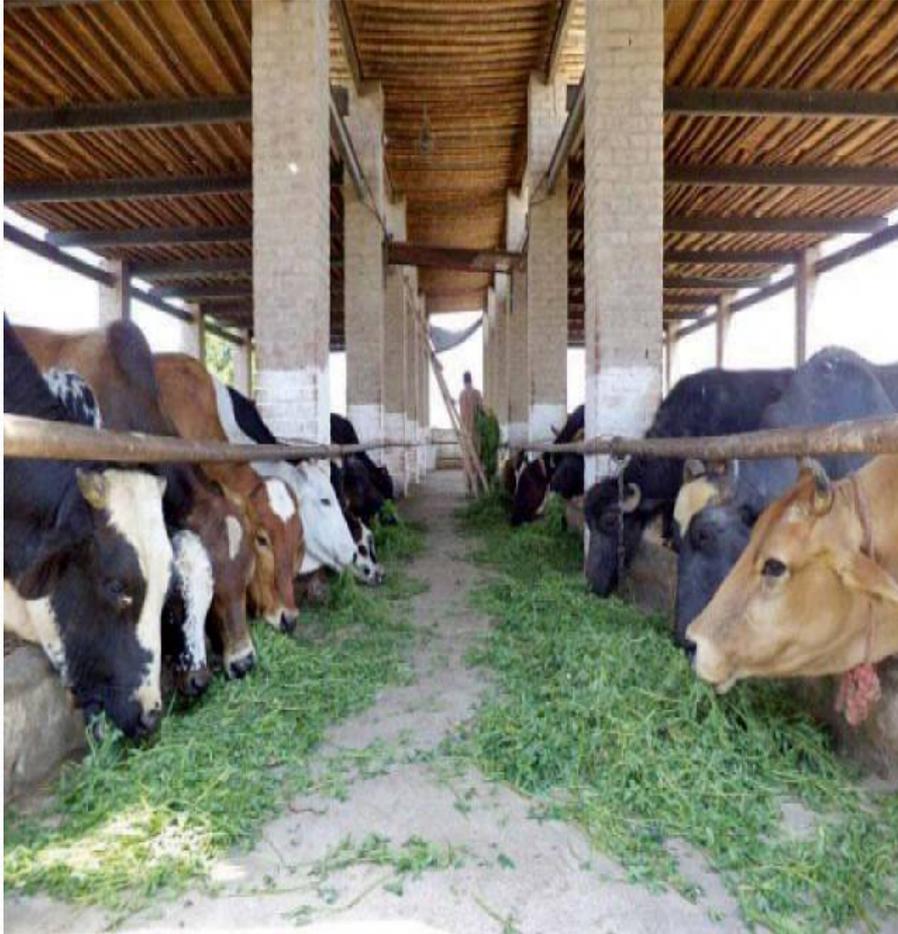


FDA CVM's ANTIMICROBIAL RESISTANCE

HISTORY

- 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



#1

A LEGAL VFD AND RX ANTIMICROBIAL DRUG ORDER RELIES ON THESE THREE ENTITIES

Veterinarian



Producer



Distributor



#2

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)

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

- RESPONSIBILITY ESTABLISHED
- SUFFICIENT KNOWLEDGE AND TIMELY VISITS
- AVAILABILITY

3

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

#4

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

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REFERENCES

- FDA Center for Veterinary Medicine VFD website:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

- MDA Animal Health website:

<http://mda.maryland.gov/AnimalHealth/Pages/default.aspx>

- **FDA Guidance #233-VFD Common Q&A and VFD Order Examples:**

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM474640.pdf>

- FDA Compliance guide for minor species section 615.115:

<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074659.pdf>

MARYLAND LAW

SENATE BILL 422 AND HOUSE BILL 602 KEEP ANTIBIOTICS EFFECTIVE ACT OF 2017

KEY POINTS TO THE LAW

- Keep Antibiotics Effective Act of 2017 became a law on October 1, 2017
- On December 1, 2019. 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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DISCUSSION

