

# Medically Important Antimicrobials in Animal Agriculture

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## Honey Bees



# Outline

- Take Home
- What Changed?
- Affected Products
- Sources of Information
- Take Home

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# Take Home



- Beginning on January 1, 2017, the use of medically important antimicrobials requires an order from a licensed veterinarian to authorize their use.
- For honey bees, this applies to:
  - oxytetracycline,
  - tylosin, or
  - lincomycin

# Outline



- Take Home
- What Changed?
  - Medically Important
  - Effective Dates
  - Order
  - Licensed Veterinarian/VCPR
  - Extralabel Use
- Affected Products
- Sources of Information



What changed?

Medically Important Antimicrobial

An antimicrobial that is important to human medicine.

The regulatory status of Fumagillin is not changed due to this action.



# What changed? Effective Date

1 January 2017:

Medically important antimicrobials that were labeled over-the-counter (OTC) now require an order from a licensed veterinarian authorizing their use.

# What changed? Marketing Status

## VFD Medicated Feed

(21 CFR part 558)

- *Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.*

## Oral Dosage Forms (Medicated Drinking Water)

(21 CFR part 520)

- *Federal law restricts this drug to use by or on the order of a licensed veterinarian.*





What changed?  
Orders  
Authorizing use

Veterinary Feed Directive  
Prescription



What changed?

Orders

## Veterinary Feed Directive

Medically Important Antimicrobials regulated by CVM/FDA as new animal drugs for use in animal feeds. (21 CFR part 558)

Authorizes the client to obtain and use the VFD medicated feed.

# What changed? Orders

## Prescription

Medically Important Antimicrobials  
regulated by CVM/FDA as oral  
dosage form new animal drugs.

(21 CFR part 520)

# What changed? Licensed Veterinarian

The veterinarian issuing the VFD must:

- (i) Be licensed to practice veterinary medicine; and

# What changed? Licensed Veterinarian

The veterinarian issuing the VFD must:

- ... (ii) Be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) ...

(21 CFR 558.6(b)(1))



# What changed? Extralabel Use

- Licensed veterinarians have limits on orders authorizing the use of approved drugs in animals.

# What changed? Extralabel Use

- (a) Extralabel use means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. ...

(21 CFR 530.3(a))

# What changed? Extralabel Use

## Limitations of Extralabel Use

- ..., the following specific extralabel uses are **not permitted** and result in the drug being deemed unsafe within the meaning of section 512 of the [FD&C] act:



# What changed? Extralabel Use

## Limitations of Extralabel Use

...

- (a) Extralabel use in an animal of an approved new animal drug or human drug by a **lay person (except when under the supervision of a licensed veterinarian)**;

# What changed? Extralabel Use

## Limitations of Extralabel Use

...

- (b) Extralabel use of an approved new animal drug or human drug **in or on an animal feed**;

# What changed? Extralabel Use

## Limitations of Extralabel Use

...

- (c) Extralabel use resulting in any **residue** which may present a risk to the public health; and

# What changed? Extralabel Use

## Limitations of Extralabel Use

...

- (d) Extralabel use resulting in any **residue** above an established safe level, safe concentration or tolerance.

(21 CFR 530.11)

# Outline



- Take Home
- What Changed?
- Affected Products
  - VFD Medicated Feed (21 CFR Part 558)
  - Rx Oral Dosage Form New Animal Drugs (21 CFR Part 520)
- Sources of Information



# Affected Products

## VFD Medicated Feed

- Oxytetracycline
  - (21 CFR Sec. 558.450)

- Examples:
- NADA
- N138-938
- N008-804
- N095-143

# Affected Products

## VFD Medicated Feed

(21 CFR 558.450)

- Active Ingredient: Oxytetracycline
- Indication: For control of American Foulbrood caused by *Paenibacillus* larvae and European Foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

# Affected Products

## VFD Medicated Feed

- Amount: 200 mg/colony
- Limitation: Remove at least 6 weeks prior to main honey flow.





# Affected Products

## VFD Medicated Feed

- By State:
  - VFD Distributor Notification List:  
<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM096059.pdf>
  - Approved Medicated Feed Mill Licenses:  
<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM089534.pdf>



# Affected Products

## VFD Medicated Feed

- Extralabel Use: Prohibited



## Affected Products

# Rx Oral Dosage Form New Animal Drugs

- 21 CFR:
  - 520.1660d: Oxytetracycline
  - 520.2640: Tylosin
  - 520.1260c: Lincomycin



## Affected Products

# Rx Oral Dosage Form New Animal Drugs

## Oxytetracycline hydrochloride

(21 CFR 520.1660d)

- Examples:
  - A/NADA
  - N008-622
  - A200-026
  - A200-146
  - A200-247 \*

## Affected Products

# Oral Dosage Form New Animal Drugs

- Active Ingredient: Oxytetracycline
- Indication: \* For control of American Foulbrood caused by *Paenibacillus* larvae.

## Affected Products

# Oral Dosage Form New Animal Drugs

- Amount: 200 milligrams per colony, administered via either a 1:1 sugar syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture.
- Limitation: ... Remove at least 6 weeks prior to main honey flow.



# Affected Products

## Rx Oral Dosage Form New Animal Drugs

### Tylosin tartrate

(21 CFR 520.2640)

- Examples:
  - A/NADA
  - N013-076
  - A200-473 \*
  - A200-455 \*



## Affected Products

# Oral Dosage Form New Animal Drugs

(21 CFR 520.2640)

- Active Ingredient: Tylosin tartrate
- Indication: For the control of American Foulbrood (*Paenibacillus* larvae).



## Affected Products

# Oral Dosage Form New Animal Drugs

(21 CFR 520.2640)

- Amount: Mix 200 milligrams tylosin in 20 grams confectioners/powdered sugar. Use immediately. Apply (dust) this mixture over the top bars of the brood chamber once weekly for 3 weeks.

## Affected Products

# Oral Dosage Form New Animal Drugs

(21 CFR 520.2640)

- Limitation: The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey.  
Complete treatments at least 4 weeks before main honey flow.



# Affected Products

## Rx Oral Dosage Form New Animal Drugs

### Lincomycin powder (21 CFR 520.1263c)

- Examples:
  - A/NADA
  - N111-636
- There are no generic approvals for this drug product due to the honey bee claim being protected under marketing exclusivity.



## Affected Products

# Oral Dosage Form New Animal Drugs

(21 CFR 520.1263c)

- Active Ingredient: Lincomycin powder
- Indication: For the control of American Foulbrood (*Paenibacillus* larvae).



## Affected Products

# Oral Dosage Form New Animal Drugs

(21 CFR 520.1263c)

Amount: Mix 100 milligrams lincomycin with 20 grams confectioners'/powdered sugar and dust over the top bars of the brood chamber once weekly for 3 weeks.



## Affected Products

# Oral Dosage Form New Animal Drugs

(21 CFR 520.1263c)

- Limitation: The drug should be fed early in the spring or late in the fall and consumed by the bees before the main honey flow begins to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.



Affected Products

# Oral Dosage Form New Animal Drugs

Extralabel Drug Use

May be allowed, if in compliance with 21  
CFR part 530

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# Sources of Information

Approved Applications: AnimalDrugs@FDA:  
<https://animaldrugsatfda.fda.gov/adafda/views/#/search>

BlueBird labels:

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm081795.htm>

eCFR: <http://162.140.57.127/cgi-bin/ECFR?page=browse>

VFD Distributors & Licensed Feed Mills:

<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM096059.pdf>

<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM089534.pdf>

# Sources of Information



OMUMS:

[http://www.fda.gov/animalveterinary/resourcesfor  
you/animalhealthliteracy/ucm189540.htm](http://www.fda.gov/animalveterinary/resourcesforyou/animalhealthliteracy/ucm189540.htm)

[AskCVM@FDA.HHS.GOV](mailto:AskCVM@FDA.HHS.GOV)

Use of Medically Important  
Antimicrobials, including  
oxytetracycline, tylosin, and lincomycin  
in honey bees,  
beginning 1 January 2017 requires an  
order from a licensed veterinarian  
authorizing their use.

