

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>

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.

