Department of
Animal Science

BEEKEEPERS AND VETERINARIANS WORKING TOGETHER TO ENSURE APPROPRIATE USE OF ANTIMICROBIALS

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The US Food and Drug Administration has created new requirements regarding how medically important antimicrobials can be administered to food-producing animals via feed and water. These changes are part of the FDA's strategy to foster antimicrobial stewardship in food-producing animals to slow or prevent potential for development of bacterial resistance to antimicrobial drugs.

Background

FDA's most recent antimicrobial stewardship efforts were publically launched in 2012 with the publication of Guidance for Industry (GFI) 209 "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals"[1] This guidance represented the FDA's current thinking on this topic and recommended adoption of two principles that would promote the judicious use of medically important antimicrobial drugs in food-producing animals:

• Limit medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health.

• Limit medically important antimicrobial drugs to uses in food-producing animals that include veterinary oversight or consultation.

With the publication of Guidance for Industry 209, the FDA focused on removing production claims of medically important antimicrobials while increasing greater veterinary oversight by changing the status of formerly over-the-counter antimicrobials now either to prescription or to a veterinary feed directive, also known as a **VFD**.

In 2013, the FDA published the follow up guidance GFI 213 "New Animal Drugs and New Animal Drug Combination Products, Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209" [2] GFI 213 outlined how animal drug sponsors of approved medically important antimicrobials that were administered through medicated feed or water could voluntarily remove indications for use related to growth promotion from their product labels, and to bring the remaining therapeutic uses of these products under the oversight of a veterinarian by the end of December 2016.

The FDA announced in January 2017 that it successfully completed the implementation of GFI 213 and all affected drug applications either aligned with the recommendations outlined in GFI 213 or their approvals were voluntarily withdrawn.

So What Does This Have to Do With Honeybees?

Honeybees are classified as food-producing animals by the federal government because products from apiculture enter the human food chain (e.g., honey). FDA designates honeybees as minor species, along with zoo animals, sheep, goats, bison, catfish and several others. Minor species are all animals that are not major species (cattle, pigs, chickens, turkeys, horses, dogs and cats). Animal drugs for minor species, including honeybees, are subject to those same requirements that FDA has published for ensuring appropriate use in major animal species.

What that means is that antimicrobials deemed medically important that were previously sold for treatment of honeybee diseases are **no longer available** over-the-counter. For beekeepers, this affects ordering antimicrobials for controlling foulbrood, in particular oxytetracycline (Terramycin), tylosin tartrate (Tylan) and lincomycin (Lincomix). These antimicrobials now need to be authorized by a veterinarian through either a prescription or a veterinary feed directive.

Veterinary Feed Directive

The FDA defines VFD drugs as new animal drugs intended for use in or on animal feed, which are limited by an approved application, conditionally approved application or index listing to use under the professional supervision of a licensed veterinarian. In order for animal feed containing a VFD drug to be fed to animals, a licensed veterinarian must first issue an order, termed a VFD.

Whether a beekeeper requires a prescription or VFD is based on the labeling of the antimicrobial. At this time, there is only one antimicrobial formulation for honeybees that uses a VFD (oxytetracyline) and three antimicrobials that are prescription based (oxytetracycline, tylosin tartrate, and lincomycin) farad.org/vetgram/bees.asp.

Antimicrobials will still be available to treat honeybee diseases; however, beekeepers now need to consult with a licensed veterinarian who will then issue either a VFD or prescription if appropriate.

Additionally, for a VFD or prescription to be considered legal, the veterinarian and the beekeeper must have a valid veterinarian-client patient relationship (VCPR). In Tennessee, the State VCPR definition applies for a lawful VFD (fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM464530.pdf) and includes the following key elements:

- The veterinarian has assumed responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, has obtained informed consent, and the client has agreed to follow the veterinarian's instructions.
- The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal
- The veterinarian has seen the animal within the last 12 months or is personally acquainted with the keeping and care of the animal, either by virtue of an examination of the animal or by medically appropriate visits to the premises where the animal is maintained within the last 12 months.
- The veterinarian is readily available or has arranged for emergency coverage for follow-up evaluation in the event of adverse reactions or the failure of the treatment regimen.
- The veterinarian must maintain medical records as required by the board of veterinary medical examiners.
- The VCPR cannot be established or maintained solely by telephone or other electronic means. For veterinarians, this includes physically visiting the apiary and examining hives and honeybees, and not just phoning in a prescription. Though follow up may be by other means once a valid VCPR has been established (e.g., email with photos, telephone, FaceTime, Skype, etc.).

How Does a Beekeeper Locate a Veterinarian?

How does a beekeeper locate a veterinarian, or how does a veterinarian inform beekeepers that they are interested in treating beehives? One way is to visit the Honey Bee Veterinary Consortium homepage (hbvc.org) and click on find a vet.

Summary

The implementation of the FDA's GFI #213 is a significant milestone in national efforts to address the use of medically important antimicrobials in food-producing animals. As a result of changes in FDA policy and updates to the VFD rule, the use of medically important antimicrobials — including oxytetracycline, tylosin and lincomycin in honeybee hives — now requires either a prescription or a VFD order from a licensed veterinarian authorizing their use. To access these antimicrobials, a beekeeper will have to work with a veterinarian and establish a valid VCPR.

The FDA's Center for Veterinary Medicine also has developed both an informative slide set and a series of questions and answers providing greater detail regarding uses of medically important antimicrobials in animal agriculture and honeybees:
FDA slide set:
fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM569965.pdf
FDA Questions and Answers — Using medically important antimicrobials in bees:
fda.gov/animalveterinary/developmentapprovalprocess/ucm589399.htm

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