

**Resource Information Regarding Antibiotics and Honey Bees and the Change in FDA Compiled
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Veterinary Feed Directive (VFD), January 1, 2017

December 12, 2013, the Food and Drug Administration (FDA) published a proposed rule to revise the Veterinary Feed Directive (VFD) regulations and by June of 2015, FDA had published a Final Rule. More recently, FDA provided specific guidance for preparation and content of VFD and Veterinary-Client-Patient-Relationship (VCPR) forms. By January 1, 2017, all of the changes had been done, and the FDA Food Safety Modernization Act, as well as the National Action Plan for Combating Antibiotic Resistant Bacteria took effect. This new Act more or less applies to any food-producing animals (cattle, pigs, poultry, fish ...), including honey bees! The overall goal is to limit and decrease the amount of antibiotics in the food that we consume.

In simple terms, that means that bees and their beekeepers now need veterinarians. Also, antibiotics can only be obtained by prescription or a veterinary food directive on written order by a veterinarian. Over-the-counter sales of antibiotics have more or less been removed (antibiotics are no longer available at stores like Murdoch's in Montana) and advertising or claims of growth promotion are now prohibited.

Up until January of this year, any US beekeeper could easily buy antibiotics from bee equipment suppliers, local farm and ranch stores, or from the internet. They could then treat their own colonies with these products, either for prophylactic purposes (e.g., oxytetracycline for control of European Foul brood) or tylosin treatment of oxytetracycline-resistant foul brood. There was, however, little or no use of lincomycin by beekeepers, although this antibiotic apparently has been approved for use in beehives since 2012.

Under the new rule of January 1, beekeepers can obtain three antibiotics from a veterinarian for the treatment of bacterial diseases of bees, primarily the two known foul broods. Depending on the antibiotic and method of administration, the beekeeper either needs a prescription for water soluble forms (oxytetracycline, tylosin, or lincomycin) or a Veterinary Feed Directive for dry, powdered forms (oxytetracycline as a sugar dust) of the antibiotic. The prescription or VFD must be issued by a licensed veterinarian. The actual antibiotic products can only be obtained from the veterinary clinic, a licensed pharmacist, or a licensed and approved supplier such as Western Bee in Polson.

What is not commonly known or clearly explained in the FDA Directive is that each beekeeper needs to set up a formal patient relationship with a veterinarian (VCPR). FDA says: In "order for a VFD to be lawful, the veterinarian issuing the VFD must:

- (I) Be licensed to practice veterinary medicine; and
- (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) as defined by the State.

Further digging into the rules, it is clear that if a state has not established VCPR forms or guidelines for a VCPR form, federal guidelines shall be followed. This summer, leaders of the Montana Beekeepers State Association met with the Montana Board of Veterinary Medicine in Helena to discuss this new rule and presented to the Board an example VCPR form used by Ohio. The Montana Board did not object to the Ohio form. Subsequently, written permission was obtained from Ohio to use their form - with modifications - mainly small changes in language and definitions to make the form more applicable to bees and apiaries in Montana. The Veterinary Board also agreed on a need for training and guidance for the state's veterinarians, who are licensed by the Montana Board. Clearly, most veterinarians and the state licensing board never anticipated having bee as patients. Apparently, only veterinarians providing service for herd animals like cattle herds were had much familiarity, knowledge, or prior use of VCPRs.

Everyone seemed to agree that an example VCPR form would be helpful to all parties (attached to this overview).

Please note, none of this should have been a surprise – it's been in the works since 2013, nor was it motivated as a profit making scheme by veterinarians. Basically, neither beekeepers nor veterinarians anticipated that the directive would include bees. Nor is it likely to be rescinded, changed, or modified to exclude bees. The goal is to ensure that antibiotics, and only the proper antibiotic, at correct dosage and application, for the appropriate bacterial disease are authorized by a licensed veterinarian; when needed, for the proper purpose, and in the amounts needed. Hoarding of antibiotics and carry-over from year to year should not occur. The beekeeper receives the amount needed for the time needed and for the number of colonies that need treatment.

The advice of the Montana Board of Veterinary Medicine was that each beekeeper needs to establish a patient (client) relationship with a veterinarian. This relationship can be established and documented by a fully completed VCPR, for a stated time period, and signed by both parties. In addition, each party should retain a copy of the VCPR for their records. Since few veterinarians have any training in bees, bee diseases, bee colony inspection, or how to safely work bees, the advice from the Board is that the beekeeping community may have to 'train' the veterinarians.

Frankly, that seems to be a rather risky approach – having beekeepers of unknown experience teach their veterinarians. UM's School of Extended and Lifelong Learning could provide this training, the State Entomologist, and many of our commercial or long-term smaller scale beekeepers, but letting anyone who keeps bees, regardless of experience, train their veterinarian is worrisome. This is not likely to be a problem to our multi-generational, commercial beekeeping families, most of whom have other livestock and an established relationship with a veterinarian. The bigger issue, which remains to be resolved, is how are hobby and small scale beekeepers going to find a veterinarian who is: (1) Who is qualified to work, inspect, and diagnose bee diseases, (2) Who is willing to add bees to their services, and (3) Who will make house calls and/or provide their services for an affordable fee. This is not a trivial issue. Reading a national listing of veterinarians who have listed themselves as providers of services to beekeepers, for western Montana, the closest listing is a veterinarian in the Tri-Cities area of Washington.

The other advice from the Veterinary Board, do not call a veterinarian and start the conversation by stating that you 'need a prescription or a VFD for antibiotics for your bees and you need it right away'. In essence, you are asking the veterinarian to violate the new FDA directive, especially if the veterinarian doesn't know you. Instead, schedule a visit to discuss the new rules and to establish a VCPR.

My advice, finding a veterinarian to provide service to bees can be difficult. All of this is new to them, and many are justifiably concerned that their license could be suspended or revoked if they inadvertently break the rules. For the small scale beekeepers and for the local bee clubs and associations, I recommend making visits to local veterinarians by your more experienced beekeepers, each taking along a copy of the example VCPR. Use that as a starting point to establishing a veterinarian-client-patient-relationship to be formalized by a signed VCPR.

UM's School of Extended and Lifelong Learning, working in collaboration with the Montana State Beekeeper's Association, the State Entomologist, the Montana Board of Veterinary Medicine, the Montana Veterinary Medical Association, and others is continuing to explore what types of training are needed for veterinarians, in what forms, where, and when – but it is a continuing dialogue. The basic issues are safely working with and around bee colonies and being able to diagnose more than just foul brood. The good news in all of this – bees can use veterinarians; but the topic is far more complex than simply antibiotics and foul brood. Bees in the USA are subjected to over 20 viral infections, at least two bacterial foul broods, two microsporidian *Nosema* species, two species of mites with a third expected to occur in the near future, small hive beetles, wax moths (two species), and other pests and diseases.

Information and Educational Resources:

Florida

Florida's bee inspection and extension specialists put together a 30-minute video that covers the FDA ruling, honey bee diseases in FL (which are mostly the same as in Montana), and symptoms and treatments of the relevant bee diseases. The video can be accessed at:

<https://www.youtube.com/watch?v=Vqtwawz-zT4>

Having watched the video, here are some resource links and notes with a description at the end of what Florida is planning in response to this recent ruling and how Montana could do much the same.

FDA Center for Veterinary Medicine

<https://www.fda.gov/AboutFDA/Transparency/Basics/ucm193613.htm> - an overview of FDA/CVM with a picture of "Bee" on a Flower that is actually a fly.

<https://www.fda.gov/animalveterinary/resourcesforyou/animalhealthliteracy/ucm309134.htm> – FDA 'Helping... Bees' – overall a reasonable overview that includes the three antibiotics approved for use in bee colonies, a description of American Foulbrood, but surprisingly totally ignores European Foul Brood.

FDA's "help for bees" displays a naïve knowledge of bees and reflects the almost universal lack of training of US veterinarians with respect to agricultural social insects.

Ohio – a proactive state, probably because of the Ohio State University Bee laboratory and the presence of a Honey Bee Supply firm that was recently bought and is managed by three veterinarians.

Ohio also provides an overview of the FDA Directive <http://www.ohiostatebeekeepers.org/resources/ohio-fact-sheets/antibiotics-honey-bees/>. This fact sheet that is very informative. However, it does reflect Ohio law, so there are some fine points that would be different for Montana.

Florida

<http://blogs.ifas.ufl.edu/entnemdept/2016/12/23/new-year-new-rule-look-fda-ruling-prescriptions-honey-bees/>, December, 2016 - an easy to understand description of the changes and issues, written by someone who understands beekeeping. Florida is planning a program that will respond to the needs of its ~ 4300 beekeepers, many of whom are small scale, but some of which are large scale commercial beekeepers. A beekeeper would go to:

- 1) The State Apiary Inspection online resource and enter relevant client information (type of foul brood, number of colonies, location, etc.
- 2) The Florida office of Apiary Inspection would then complete the parts of the form affirming that the beekeeper is registered, dates bees inspected, etc.
- 3) Assuming that the Office of Apiary Inspection approves the client request, the form would then be forwarded to a State Veterinarian, who issues the appropriate prescription or VFD.
- 4) Dr. Jamie Ellis is working on providing a training program for Florida's Veterinarians.

Montana could easily do much the same, having a State Entomologist, Bee Inspections, a State Bee Act, Online Beekeeping Programs, and Honey Bee Experts at both UM and MSU.

Other Resources:

A good, convenient, and free resource concerning bee pests and diseases can be found in an Alberta Government Smart Phone app,

Android: <https://play.google.com/store/apps/details?id=ca.ab.gov.beehealth&hl=en>

iPhone: <https://itunes.apple.com/us/app/bee-health/id1005231410?mt=8>

Veterinary Client / Patient Relationship (VCPR)

Agreement for Montana Honey Bee Colonies

Name of Clinic:

This agreement reaffirms a relationship between the veterinarian of record (VoR) and the client that they are committed to use drugs in a safe, effective and appropriate manner, which includes avoiding residues in honey.

- No medication will be used in a manner that is not listed on the label unless directed by the veterinarian and written in the treatment protocols for the client by the VoR.
- The client and veterinarian agree to keep accurate and detailed treatment records (i.e., apiary ID, date, drug, dosage, route of administration, personnel involved).
- Regardless of where drugs (prescription or over-the-counter) are obtained their use should be consistent with this agreement.
- The veterinarian will provide consultation and oversight of treatment records and drug use for client apiaries.
- All withholding times between drug administration and honey flows will be provided by the veterinarian and followed by the client or representative.
- The client is responsible to immediately notify the veterinarian of any honey residue violations.
- All medications will be stored, labeled, and administered only to colonies within registered apiaries according to state and federal regulations.
- Prescription medications can only be used for colonies within registered apiaries for which they were prescribed.

The VoR is unique to all other veterinarians working with the client in that this veterinarian is responsible for providing appropriate oversight and treatment protocols of all drug usage. All other veterinarians working on the farm should notify the VoR of their recommendations and/or actions regarding treatment protocols.

This document is to be reviewed annually by the client and the VoR.

Client: _____ Veterinarian of Record (VoR): _____

Signed: _____ Signed: _____

Date: _____ Date: _____