

Tips for complying with the updated VFD rule

An interview with JON SCHAEFFER, DVM, director of poultry technical services, Zoetis



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Q: Under the updated veterinary feed directive (VFD), veterinarians must keep original VFDs and producers and feed mills must keep copies for 2 years. Does this mean integrated companies need to keep the same VFD on file in three different places?

JS: Fortunately, no. According to FDA, it's acceptable for integrated companies to keep VFDs in one place, provided the veterinarian, producer and feed mill all have easy access and can provide them if requested by FDA investigators.

Q: Let's say our veterinarian is having a really busy day and we receive a VFD that's missing a few minor details. Can we proceed with the order and fill in the blanks later?

JS: Absolutely not. FDA has made it clear that forms must be completed in full before you can use VFD medications.

Q: What should poultry growers do if the feed mill can't fill an entire VFD order that's urgently needed to treat sick birds?

JS: Under FDA rules, one feed mill is supposed to fill the entire VFD order. However, if the mill runs out or has an equipment breakdown and two mills are needed to fill the order, the producer and the two feed mills should document this special circumstance in writing so it is clear to FDA inspectors.

Q: Is there a grandfather clause for premixes and other medicated feeds with old over-the-counter (OTC) labels that will be transitioning to VFD status?

JS: No. Any feed products containing medications transitioning from OTC to VFD status will still require a VFD from a licensed veterinarian as of January 1, 2017, even if they were made in 2016 under the old OTC label. It's expected that animal-health companies will provide stickers that can be used to update old labels.

continued

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Informal communication from William T. Flynn, DVM, MS, deputy director for science policy, FDA Center for Veterinary Medicine, to Sheldon R. Jones, Farm Foundation, NFP. March 4, 2016.

#120 Guidance for Industry Small Entity Compliance Guide Veterinary Feed Directive Regulation Questions and Answers

Q: Under the new rules, is it OK to use VFD medications in combination with OTC medications?

JS: Yes, as long as the VFD medication is approved for use in combination with that OTC product and the veterinarian writing the VFD has also approved the combination for use in your flock.

Take chlortetracycline, for example. It's a medically important antibiotic that will require a VFD, but its label says it may be used in combination with the anticoccidials salinomycin, decoquinate, robenidine or zoalene, all of which will remain OTC medications. You will, therefore, need a VFD if any of these OTC products are combined with a VFD medication.

Q: Can a photo or video be used to verify the veterinary-client-patient relationship (VCPR) needed to obtain a VFD?

JS: No. Licensed veterinarians writing VFDs must comply with the VCPR criteria outlined by either state or federal authorities. State definitions are recognized by FDA if they include key elements of the federally defined VCPR; one of those key elements requires veterinarians to have sufficient knowledge of the patient by virtue of patient examination and/or visits to

the facility where those patients — in this case, flocks — are managed.

Q: Will there be penalties for noncompliance with the updated VFD rule?

JS: Possibly. Initially, FDA is expected to issue warning letters for minor or unintentional violations. However, the agency says major and flagrant violations could result in injunctions, seizures and even criminal charges involving jail time and hefty fines. In a worst-case scenario involving repeat violations or violations intended to defraud or mislead, the penalty could be 3 years in jail, fines up to \$10,000 or both.

Q: How does FDA plan to check on compliance with the updated VFD rule?

JS: FDA will engage in what it calls “risk-based general surveillance as well as for-cause inspection assignments” to ensure compliance. The agency also plans to work closely with state regulatory partners and boards of veterinary medicine.

However, FDA has emphasized that its first priority is education, which will help ensure that all stakeholders are able to comply with the updated VFD rule.