

PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

# Implementation of FDA's new antibiotic rules

On Wednesday, December 11, 2013, the US Food and Drug Administration (FDA) announced two coordinated actions based on its belief “that production use indications such as ‘increased rate of rate of weight gain’ or ‘improved feed efficiency’ are no longer appropriate for the approved conditions for medically important antimicrobial drugs.”

First, it released Guidance for Industry #213 (GFI #213) titled “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” (<http://tinyurl.com/7cx4q72>).

Second it issued a proposed rule named, Veterinary Feed Directive, “to amend its animal drug regulations regarding veterinary feed directive (VFD) drugs” (<http://tinyurl.com/pyzb6k3>). “As FDA begins to implement the judicious use principles for medically important antimicrobial new animal drugs approved for use in food-producing animals, based on the framework set forth in Guidance for Industry (GFI) #209 (published April 13, 2012), it is critical that the Agency makes the VFD program as efficient as possible for stakeholders while maintaining adequate protection for human and animal health.”

In GFI #213, the FDA states that it “will be working with affected drug sponsors who wish to voluntarily withdraw approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products.” As the FDA notes, “It is important to note that any extralabel use of medicated feed is not permitted by law.... Neither veterinarians nor their clients may use, or direct the use of, a medicated feed in an extralabel manner. Therefore, when production claims for medically important antimicrobials are voluntarily removed from the approved labeling of these drugs, consistent with the judicious use principles of GFI #209, any further use of a drug without a production claim in medicated feed for production purposes will be considered an extralabel use and, thus, illegal.”

Drug sponsors are given a three month period in which to indicate whether or not they intend to file an application to remove production claims from the relevant drug labels. There will then be a 3-year phase-in timeframe to 1) “provide sufficient time for the necessary changes to the existing VFD requirements to be developed and implemented through notice and comment rulemaking,” and 2) “provide time for animal

drug sponsors to make these changes in an efficient and practical manner, and for other stakeholders to prepare for the resulting changes in management/business practices.”

The “FDA intends to keep the public apprised of progress. First, FDA is making public on its website a listing of all antimicrobial products affected by the guidance. Second, FDA intends to notify affected drug sponsors and, following the 3-month notification period, FDA intends to publish summary information to provide an indicator of the level of engagement of affected drug sponsors in the voluntary process.... The public will be notified of completed changes to affected products through publication of approval of supplemental new animal drug applications.”

In the VFD proposed rule, the FDA notes that “currently, the vast majority of the antimicrobial animal drug products that are the focus of GFI #209 are feed-use drugs—that is, they are products approved for use in or on animal feed. All but a few of these products are currently available OTC (over-the-counter) without veterinary oversight or consultation and would be affected by the recommendation to switch to VFD status.”

Under the proposed rule “a VFD may only be issued by a licensed veterinarian for the use of VFE drugs in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements.”

“When completing the VFD order, the veterinarian needs to make sure the VFD is consistent with the conditions of use in the approved application, conditionally approved application, or index listing; similarly, when filling a valid VFD, the medicated feed manufacturer must assure that the final medicated feed is manufactured and labeled in conformity with both the VFD and the approved, conditionally approved, or indexed conditions for use. If the conditions of use specified on a VFD are not in conformity with an approved new animal drug application, conditionally approved application, or index listing, the VFD is considered invalid and the medicated feed described on the VFD may not be manufactured or distributed.”

The proposed VFD amendments will allow current OTC drugs that have the lowest potential for the creation of unsafe residues in edible animal tissue to continue to be produced in unlicensed facilities even though they will now need a VFD. The amendments will also reduce the time period that VFD-feed manu-

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facturing records must be kept from 2 years to 1 year.

The FDA makes it clear that “if, after the period of evaluation of the three year phase in, [it] determine[s] that adequate progress has not been made, [it] will consider whether further action under the existing provisions of the [Food Drug and Cosmetic] Act may be appropriate.

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