

DAIRY VETERINARY NEWSLETTER

May 2023

FDA GFI #263 Takes Effect June 11, 2023 - What does this mean for Veterinarians?

Nearly 4 years after the U.S. FDA released its first draft of the guidance for industry (GFI) #263, and almost 3 and a half years since the comment period was initially stated to end, FDA GFI #263 will take effect on June 11, 2023. Such a date, especially falling on a Sunday, for the implementation date of an FDA regulatory change is something unusual. What is this guidance about and what is it intended to do?

A previous FDA document from 2019, no longer available, regarding GFI #263 said, “This guidance is intended for - - animal drugs containing medically important antimicrobials for use in non-food (companion), food-producing animals, or both, that are currently approved with over-the-counter marketing status - - to [change] use of these drugs to prescription marketing status.”

Updated on May 15, 2023, the FDA Frequently Asked Questions introduction to GFI 263 states: “[GFI] #263 is part of a broader effort by FDA to combat antimicrobial resistance (AMR), a serious threat to animal and public health. - - Using antimicrobials judiciously, in all settings, can help slow the rate at which AMR develops.”



The link to all current FAQ's and links to other information about GFI #263 are found at: <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/gfi-263-frequently-asked-questions-farmers-and-ranchers> Some further information from other FAQ answers is included below.

Likely impact on dairy and other veterinarians

The true impact of regulatory changes such as this are never certain until some time passes after implementation. However, the FDA is clearly continuing on its path of at least theoretically putting more control of antimicrobial treatment of all animals into the hands of veterinarians.

For years, the FDA has urged “drug sponsors” - which when the Veterinary Feed Directive (VFD) was implemented turned out to mean drug manufacturers - to make voluntary labeling changes of many antibiotics to prescription status. One of the recent FAQ answers states, “When animal drug sponsors make the voluntary labeling changes recommended in GFI #263, the relatively small number of medically important antimicrobial

drugs that are currently available over the counter (OTC) would then require a veterinarian's prescription (Rx). Obtaining these drugs under a veterinarian's supervision can help guide the judicious use of antimicrobials and slow the development of AMR because veterinarians have specialized training and experience."

This change has a similarity to past regulatory changes such as reductions in the somatic cell count legal limit in bulk milk, the Animal Medicinal Drug Use Clarification Act (AMDUCA), the VFD, and others. Despite considerable effort by government, pharmaceutical manufacturers and distributors, agricultural feed and supply retailers, and university extension programs, I am finding that many dairy producers I ask about GFI # 263 or what it means in terms of purchasing antibiotics are unaware that it is coming. It will not be a surprise if during the first days or weeks of this policy taking effect, some owners of all animal species will be unaware and possibly upset that many antibiotics that were previously OTC drugs now require a prescription. There may well be an initial large wave of animals owners, including those with little to no previous relationships with veterinarians, asking for prescriptions for antibiotics to treat their animals.

Animal and bird species affected

What species are affected by GFI #263? "Drugs for both food-producing animals and companion animals are affected. Species impacted by GFI #263 include cattle, swine, chickens, turkeys, horses, sheep, goats, cats, and dogs." While it is not specified, I think it likely that other species such as llamas, alpacas, pet birds, etc. are also considered to fall under this new policy. As we described years ago in this newsletter, it has been clear at many conferences and presentations over the years that the FDA does not attempt to define "companion animal". Therefore the fact that all antimicrobials for all animals will be changed to Rx status probably simplifies life for dairy and food animal veterinarians, at least in one way. It will not be necessary to have OTC medications available or described as an option for some species, but Rx for others.



What drugs/products are affected?

There is a current official "List of Approved New Animal Drug Applications Affected by GFI #263". The drug list can be found within the link shown above, but also directly at:

<https://www.fda.gov/animal-veterinary/antimicrobial-resistance/list-approved-new-animal-drug-applications-affected-gfi-263>

Interestingly, the "list" document begins with a statement extolling the VFD guidelines: "- - medically important antimicrobials administered in the feed or drinking water of food-producing animals are only available for use through a licensed veterinarian." Nevertheless, no claim is made regarding reduction of use of such oral antimicrobials in animals and birds, as was the case during the first year or so after the VFD took effect. The most recent data I have seen regarding that issue showed a steady increase back toward previous levels of feed and water use of antibiotics for livestock after it declined precipitously at first. This was not a surprise to most veterinarians I know.

The list of NADA provided by FDA does not make clear the route of administration, and does not appear to be as long a list of OTC antibiotics for animals or birds as were previous such lists (e.g. the list of drugs before VFD was implemented was 28 pages long).

There are 93 products listed, containing the following 18 antimicrobials:

Cephapirin	Chlortetracycline	Dihydrostreptomycin	Erythromycin	Gentamicin
Lincomycin	Novobiocin	Oxytetracycline	Penicillin G Benzathine	
Penicillin G Procaine		Spectinomycin	Sulfabromomethazine	
Sulfachlorpyridazine		Sulfadimethoxine	Sulfamethazine	Sulfisoxazole
Tetracycline	Tylosin			

What about enforcement, including existing stocks of OTC antimicrobials?

FDA states, “As of June 11, 2023, all new affected products entering the marketplace must have prescription labeling. Affected OTC-labeled products that are already in distribution - - can be purchased over the counter until inventories deplete. - - Timelines for OTC product depletion may vary but are expected to be consistent with normal sales volume and expiration dates for a given product.”

FDA continues, “Just because a drug is prescription status does not necessarily mean you are required to purchase it directly from a veterinarian. Although certain state requirements may also apply, you may be able to purchase prescription animal drug products from various suppliers or distributors with a valid prescription provided by a licensed veterinarian. - - Although specific requirements vary by state, veterinarians are generally not required to examine each individual animal for which a prescription is issued, as long as the veterinarian has established a valid VCPR [veterinarian-client-patient relationship] with the farmer or rancher that owns or cares for the animal(s) in need of treatment.”

What constitutes a VCPR, and will it be enforced?

However, as always the question continues, what exactly is really required to constitute a valid VCPR? Is it enforced? The GFI #263 documents barely mentions VCPR, even less so than when previous antibiotic regulatory changes were adopted. FDA has never defined in any meaningful way what a VCPR requires.

Unless and until FDA and/or other agencies and authorities that regulate veterinary medicine and pharmaceuticals ever address what is really needed for a VCPR, the apparent aims of increased veterinary insight and diagnoses before use of antimicrobials in animals, birds, etc. are unlikely to be fully realized. The involvement of a veterinarian who observes the animals directly, diagnoses the disease(s) observed, including relevant clinical signs and likely differential diagnoses, and then prescribes antimicrobial drugs based on this timely familiarity with the animals does not always take place when animal owners obtain Rx drugs including antibiotics. This will continue, and quite possibly increase, unless a valid VCPR including reasonable familiarity with the disease on farms or in companion animals is both defined and enforced.

One thing is for certain; veterinarians, including those working with dairy farms, will be asked more than ever before to write prescriptions for antimicrobial drugs used in treatment of animals.

Mountain Lands Utah Veterinary Summit June 1 - 3, 2023, Park City, Utah

As reported in the previous issue of the newsletter, this year’s Utah Veterinary Summit, a conference organized by the Utah Veterinary Medical Association, has something for all veterinarians, including dairy and food animal

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veterinarians. I hope to see you in Park City, Utah at the Doubletree by Hilton Hotel - The Yarrow. The schedule and other conference information can be seen online at:

<https://vetmed.usu.edu/continue-education/annualceconference>

The link for registration for the conference is: <https://cvent.me/ArvQGB>

Please let us know your comments and suggestions for future topics. I can be reached at (435) 760-3731 (Cell), or David.Wilson@usu.edu.

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