American Lamb Council

American Sheep Industry Association
Sheepusa.org

American Wool Council

December 24, 2019

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

Submitted via Email

Re: FDA-2019-D-3614: Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to Be Available Over-the-Counter; Draft Guidance for Industry; Availability

The American Sheep Industry Association (ASI) appreciates the opportunity to provide our comments on the Food and Drug Administration's (FDA) Draft Guidance #263 for Industry providing Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products that Continue to be Available Over-the-Counter. Since 1865, ASI has been the national trade organization representing the interests of the over 100,000 sheep producers located throughout the country who produce America's lamb and wool. ASI is a federation of forty-five state sheep associations representing a diverse industry. Our organization represents the interests of the greater sheep industry as well as individual sheep producers directly impacted by the Agency's actions regarding the judicious use of medically important antimicrobials that benefit their livestock. We are cooperators in FDA's effort to ensure judicious use of antimicrobials in livestock as reflected in ASI's Sheep Care Guide that we make available to all sheep producers.

ASI appreciates the public health concern that is presented with the development of resistance to antimicrobial drugs of importance to human medicine and the resulting loss of their effectiveness as antimicrobial therapies. We also appreciate that FDA is seeking a balance between this concern and the judicious use of medically important antimicrobial drugs necessary for assuring animal health. We believe there are some factors that should be considered by the Agency to avoid unintended consequences as it moves forward with its plan to ensure appropriate and judicious use of medically important and necessary antimicrobials in livestock.

We would like to bring to the Agency's attention some important circumstances that are currently having an impact on the ability to provide adequate veterinary care to livestock and ask that the Agency consider if, and how, its recommendations, as presented in the guidance document, could worsen these circumstances. We would also ask the Agency to consider gathering information to determine the potential impact and to assist in developing a strategy to reduce potential unintended consequences.

Severe Shortage of Large Animal Veterinarians

In the US, there is a critical shortage of large animal veterinarians. This shortage is putting our nation's food supply at risk. An August 25, 2019 article published by the Associated Press (AP), cited an example in Vernon County, Missouri where one veterinarian was available for every 206,000 food animals (https://apnews.com/0da140722da043e981f3881d1b75d6c3, last visited 12/23/19). In areas of the mountain west, a veterinarian may need to travel as much as 100 miles or more to reach the producer and their livestock. Further exacerbating this situation for the sheep industry is the fact that there are very few veterinarians trained in sheep production and medicine.

In reviewing the draft guidance, we wondered what the parameters for a prescription of a current OTC product would look like? Would such a product be prescribed only for an individual animal or could a veterinarian prescribe a product to a producer based on a limited number of typical conditions that might develop during the flock production cycle? This would mean having product on hand to use in the event it is needed, such as during lambing. A per animal prescription for producers with very large numbers of animals (such as 1000 or 5000 head) could create a significant burden on a veterinarian, especially one who already must provide services to significant numbers of animals over a large area, and may result in a lack of adequate medical attention.

Depending on how the Agency's draft guidance is implemented, the administrative burden on the few veterinarians available to large animal producers could be substantial. If a producer is unable to provide necessary medication because a veterinarian cannot be reached or cannot get to the site in time, the animal is likely to suffer and even die. There must be some allowance for a trust between veterinarians and their clients that the client can administer products appropriately in these types of situations.

Further, if the burden is too much for veterinarians it could lead to their moving away from large animal practice, further exacerbating the existing shortage the nation is experiencing. Alternatively, it could result in substantial cost increases for producers. For example, in some areas of the Northeast, veterinarians charge between $75 - $150 for a simple health certificate. If similar charges are required for a prescription for necessary medical products, it could have negative consequences, particularly if a prescription is required for each animal. Producers would go out of business, and those who don't, would have animals suffer or die due to the lack of financial ability to care for them. It could also cause a potential "black market" to develop, which would be detrimental to the animals and producers, and would remove any oversight on the products that are used.

Limited Availability of Products for Use in Sheep

The availability of necessary veterinary products for use in sheep is already very limited and we have seen more and more of those products being removed from the market. New products are not being developed for use in the U.S. A contributing factor to this situation is the increasing costs that drug sponsors incur to comply with regulatory requirements.

ASI is concerned about the consequences of increased regulation. Already, because of the lack of product availability, the nation's sheep flock is afflicted with conditions that our counterparts in

other countries are able to treat with a variety of therapeutic products that we don't have available in the US. Meanwhile, our animals suffer. We must find a balance between animal well-being and the need to regulate medically necessary antimicrobials in order to preserve their effectiveness.

Extra-label Use of Products

The cost of labeling products for specific species causes many sponsors to forgo the process. Nonetheless, veterinarians will prescribe extra-label use of some products in order to treat animals. Because the available products labeled for use in sheep are limited, veterinarians have prescribed products for extra-label use to treat conditions in sheep. Will this be permitted with products currently marketed as OTC but become prescription only?

Conclusion and Request for Consideration

The current situation regarding veterinary care for livestock in rural areas poses an animal welfare concern and is a major food supply concern. Before finalizing the Guidance document, we would like FDA to seek feedback from sponsors of antimicrobial new animal drugs that are considered medically important with approval for OTC marketing that are used in minor species, such as sheep, to see if any of these products may be in jeopardy of being removed from the market if changed to prescription only. If so, would the product's loss be significant for the livestock industry? We would ask the FDA to consider that information and help develop a practical solution to ensure that this action will not pose a risk to the well-being of livestock or the viability of the nation's food supply.

Lastly, we would ask FDA to clarify two things. The first, will a prescription for antimicrobial new animal drugs with current approval as an OTC be per animal or per flock? And, the second, will extra-label use of antimicrobial new animal drugs be permitted?

Again, the ASI appreciates the opportunity to comment on this draft guidance. We would be happy to discuss the matter further if additional information is needed. We remain interested in this topic and the Agency's progress related to it.

Sincerely,

Peter Orwick
Executive Director