

National Pork Producers Council
122 C Street, NW, Suite 875
Washington, DC, USA 20001

January 5th, 2024
Dockets Management Staff
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: [Docket No. FDA-2023-D-2925] Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals; Draft Guidance for Industry

To Whom it May Concern,

The National Pork Producers Council (NPPC) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals; Draft Guidance for Industry. NPPC is the global voice for the U.S. pork industry and consists of 43 affiliated state organizations representing America's 66,000 pork producers who supply a demonstrably safe, wholesome, and nutritious product appreciated on American and international tables.

The pork industry recognizes the importance of antimicrobial stewardship in maintaining animal health and welfare and producing a safe protein product. Pork producers are committed to the judicious use of antimicrobials and utilize veterinary oversight. NPPC appreciates the FDA making the draft guidance available for comment, as this increases stakeholder engagement. NPPC recognizes the intention to describe a pathway for sponsors to add defined durations of use to the labels of products that contain medically important antimicrobials and do not currently have a defined duration of use. Although well intentioned, this draft guidance will deny the ability for a veterinarian to prescribe antimicrobials appropriately. This draft guidance will also burden pharmaceutical companies and may jeopardize access to antibiotics. NPPC also questions the inclusion of antimicrobial resistance mitigation statements, as these can be confusing and undermine the role of the veterinarian. Along with our comments, NPPC urges the FDA to work with sponsors, as these guidelines will impact their business and products used in the swine industry.

The Veterinarian's Role

Pork producers work closely with veterinarians and operate within the context of a veterinarian-client-patient relationship (VPCR). When the VPCR is established, the veterinarian works with pork producers to create health plans and protocols for the animals. The veterinarian is responsible for deciding what antimicrobial to prescribe, as well as when the product should be used and administered, which animals to medicate, and for how long. The draft guidance interferes with the veterinarian's decision-

making process by mandating a duration of use. The veterinarian is not only familiar with the animals, but they also have insight into the farm's disease history, disease prevalence and pressure, environment, risks, and the known swine disease causing pathogens. The role of the veterinarian is to use their medical knowledge in congruent with their knowledge of the patient(s), and that role is now in danger.

Maintaining Product Availability

NPPC supports access to approved antimicrobials to maintain animal health, welfare, and food safety. However, the draft guidance presents a major and detrimental potential for losing the availability of certain antimicrobials. The guidance document indicates there will be a voluntary withdrawal of approved indication or regimen with an undefined duration of use for sponsors who choose not to comply. If the process to define a duration of use for a product is too burdensome, this may be an unintended outcome. Thus, veterinarians and producers would lose access to safe and effective antimicrobials for therapeutic use for swine. Therefore, NPPC urges the FDA to simplify this process and work with pharmaceutical companies to ensure the defined durations of use are not too arduous, time consuming, or expensive. This is especially important to pioneer companies, as the responsibility for this process falls to these sponsors. If the pioneer company does not continue to manufacture the product due to a burdensome process, this will affect all generic products that were approved referencing the pioneer product. The antimicrobial products available for swine medicine are already limited, and this duration of use guidance document could further shrink the veterinarian's toolbox.

Antimicrobial Resistance Mitigation Statements

NPPC questions the inclusion of antimicrobial resistance mitigation statements on products. Although NPPC recognizes that such statements are intended to support judicious use practices, certain drugs in question are already under the supervision of a veterinarian who has established a VPCR with the producer. Veterinarians practice judicious use of antimicrobials and have the best knowledge of history and disease status of the animals they are treating. These statements can potentially take away the veterinarian's decision-making ability and are, in some cases, redundant. In addition, the use of "immediately" creates confusion, as the interpretation of would mean during the next feeding for a Veterinary Feed Directive (VFD) drug. If such statements are applied, they could limit the use of a product due to language that is not clear and does not appropriately fit production. This will cause confusion regarding when a product can and cannot be used. NPPC recommends omitting these statements and allowing the veterinarian to practice judicious use of antimicrobials through a valid VPCR.

Conclusion

NPPC appreciates the opportunity to comment on the Defining Durations of Use for Approved Antimicrobial Drugs Fed to Food-Producing Animals; Draft Guidance for Industry and looks forward to continuing to work with the FDA and other stakeholders to support antimicrobial stewardship. NPPC urges the FDA to work closely with the drug sponsors to provide a simple process to include duration of use to continue availability of products – and to allow the veterinarian to maintain their role in the decision-making process, supporting judicious use of antimicrobials. The pork industry is committed to supporting antimicrobial stewardship and producing a safe and wholesome protein product for consumers in the United States and globally.



The Global Voice for
the U.S. Pork Industry

Sincerely,

A handwritten signature in black ink, appearing to read 'Ashley Johnson'. The signature is fluid and cursive, with the first name 'Ashley' and last name 'Johnson' clearly distinguishable.

Dr. Ashley Johnson
Director of Food Policy
National Pork Producers Council