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# IMPL(ANT)ICATIONS

*New implant labeling policies and what that means for producers.*

Livestock steroid implants to increase growth rate and efficiencies have been an integral part of beef production since the 1950s. The Food and Drug Administration (FDA) and the Center for Veterinary Medicine (CVM) shoulders responsibility of regulating products used in food animal production that impact human health, including beef cattle implants.

In recent years, the FDA has acknowledged some implant products have been used in ways that are not necessarily consistent with labeling and the manner the products were initially approved.

William Flynn, DVM, CVM principal deputy director, explains that when companies seek to market a product, they submit possible conditions in which they intend to market the product.

"Our evaluation of that product to ensure that it is safe, effective, and does what it says it does, is based on that set of conditions outlined when that product was initially being developed," Flynn says.

"It became more apparent to us over time that how some of these products were being used more commonly now was not really aligning with the intended, labeled use of the product when they were evaluated."

In particular, reimplantation practices prompted concerns with FDA staff. Many implant products introduced on the market decades ago were not assessed under conditions where reimplantation was expected. While some products have explicit instructions for reimplanting, others do not.

"We evaluated products as though they would be implanted once, but it turns out, we're seeing now that some of these products are actually being used more than once," Flynn says. "So, that was really the concern — to address that issue and make sure the labels are clear so producers know what products can be used under what circumstances."

To right this obscurity, the FDA CVM is requiring updated labeling regarding implantation within a production phase. Official notices to implant sponsors and stakeholders were distributed to companies that manufacture implants beginning May 2021, with

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## William Flynn, DVM

Dr. Flynn earned a Master of Science in veterinary preventative medicine in 1987 and a Doctorate of Veterinary Medicine in 1991 from the Ohio State University.

Following several years of private veterinary practice, Flynn joined the Food and Drug Administration's Center for Veterinary Medicine (CVM) in 1993. He served in various capacities in CVM's Office of New Animal Drug Evaluation with a focus on issues for therapeutic drugs for food-producing animals.

From 2003 to 2008, he served as director of CVM's Policy and Regulations staff, and then was selected to serve as CVM's deputy director for science policy. In 2023, Flynn took his current position as the CVM principal deputy director.

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requirements that labels must have clear directives by July 1, 2023.

The FDA's mandate is not intended to affect the availability of implant products, or the practice of reimplantation.

"Reimplantation across production phases is not impacted by this," clarifies Flynn. "We want to ensure that producers are using the appropriate product in the appropriate production phase."

For example, a beef cattle implant may be labeled for use in pasture calves, but may not specify if it is approved to implant in a calf on pasture more than once. The vague labeling begs the question for end users, "Does silence mean it's okay, or does silence mean it's not okay?" Flynn observes.

He adds that regarding this rule, knowing the implant history isn't critical because a new, appropriate implant product would be used in a new production phase. Beef cattle, for instance, can still receive multiple implants across different production phases.

For example, if weaned calves are delivered to a stocker/backgrounder or feeders to a finishing yard, the purchaser often does not necessarily need to know the implant history of each animal to follow safe implant practices.

As a veterinarian, Flynn values safe and effective products available for addressing animal health needs, ensuring efficient production, and understands the important role implants play in supporting the cattle sector.

"We think it's important that we are able to stand behind these products, and therefore that's why we need to make sure that these products are, in fact, safe and effective," he notes. "We want to be able to stand up without any question and say these are safe and effective products."

This initiative proactively lessens vulnerability for the industry, ensuring producers use products correctly.

And while most of these products do not require a prescription, implants play a key role in optimizing production and influencing herd health and management. Therefore, Flynn encourages a client-patient relationship to consult veterinarians as necessary for the optimal use of any over-the-counter product like implants.

"The bottom line when it comes to considering whether to reimplant animals within a production phase is that only those products labeled as approved for reimplanting within a production phase are used," he says. "If a label doesn't specify, then it's not approved for reimplanting within a production phase." ◆