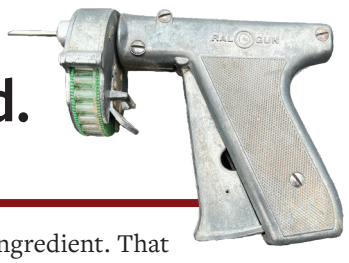
Reimplanting's Future Unclear

Revisions to FDA Guidance 191 being considered, clarified.



by Miranda Reiman, director of digital content & strategy

It's not always easy to predict how a policy change on paper will look when applied out in production.

For cattlemen, that's the case with new language in the 2008-created but newly edited Guidance for Industry (GFI) 191 from the U.S. Food and Drug Administration (FDA), said Brad Johnson, the Gordon W. Davis Regent's Chair in meat science and muscle biology at Texas Tech University.

In 2020, the FDA introduced revisions to cattle classifications and stronger language around reimplanting cattle, but the changes were not widely publicized. As the grace period of June 30, 2023, nears, nutritionists, academics and cattlemen are wondering what exactly it means to them.

"I think there's a lot of concern about why didn't the average producer hear about this, or myself as an academician? I didn't hear about it at all," said Johnson, who has spent much of his career in research in this space. "This was communication between our U.S. Food and Drug Administration and the pharmaceutical industries here in the United States; not necessarily the production level."

A big deal

The basis for the apprehension is well-founded. Implants have been an important tool for efficient cattle production for nearly seven decades, and their significance is underscored now, Johnson said.

"Obviously today, with the cost of gain where it is, small changes are worth a lot of dollars," he said. For example, a 1% change in feed efficiency in some parts of California, where feed costs are $500 per ton, is worth $14 per head, he noted.

"Our first implant was approved in 1956, Synovex® S. We still have that same implant 67 years later, the same payout mechanism, the same active ingredient. That implant has not changed," Johnson explained. "So, we've been using steroid implants effectively for almost 70 years in the United States to produce very safe, wholesome and efficient beef."

Questionable edits

With the new edits, cattle classifications are spelled out more precisely and in additional categories, such as "suckling calves" being broken into pre-ruminating calves from birth to 2 months of age and then calves that are greater than 2 months of age. Knowing that most beef cattle aren't weaned until 180-200 days, that calls into question how that will be applied to current implant labels.

"Weaned growing beef steers and heifers maintained on pasture, receiving most of their diet from grass," is self-explanatory, he noted, but that moves cattle in a true grow-yard situation to be considered the same stage as cattle in a feedyard.

"That is the one that's going to impact the majority of finishing cattle," Johnson said. "You can only use one implant — unless it's been preapproved for reimplant — you can only use one implant per stage for each of those five stages.

"As the letter of the law states, most of our implants that we have today, you can only pick one to use throughout that time frame of entering a grow yard through slaughter," he said. "We're talking about maybe 900 to 1,000 pounds of gain in that lifetime of that animal that can only be exposed to one implant over that time from a grow yard to a finishing phase."

Proof required again

No doubt pharmaceutical companies have been working to get their products relabeled, Johnson said, but the four-step process isn't always quick or simple. They must have evidence that the compound is:

- **Inherently beneficial.** "You have to prove that it's better than a single impact," he said, noting the FDA isn't swayed by the fact that cattlemen have used them for decades or that they're needed for profitability.
- **Safe for animals.** "We know they're safe, right? But you've got to go through all the steps," he said, noting they're not new formulations, so it seems redundant.
- **Not harmful to the environment.** There's been concern specifically about trenbolone acetate (TBA) finding its way into the environment and reconverting from an inactive form to an active form. Any new implants in the last two decades have had to "do a massive environment assessment prior to the approval of these newer implants the last 15 years to not only appease the FDA but also to appease the EPA (Environmental Protection Agency)."
- **Not harmful to humans.** "We've never had a violative residue with trenbolone acetate in the U.S. beef production system, but yet, still they raise that issue," he said.

Positive front

For all the concern around how these tweaks will be implemented, Johnson said there is some encouraging news.

"The pharmaceutical companies are being good chaperones of the molecule. They're going to work with FDA and try to get label changes, so we can keep doing business as usual," he said. "The fact that [the FDA] is allowing about the same level of dosages, if the right paperwork is filed, is encouraging that we're not going to lose the technology."

The recent conversation with government agencies allowed the industry to illustrate the importance of implants, Johnson noted.

"It's very vital, now more than ever, with the cost of production, that we maintain every tool," Johnson said. "As we talk about sustainability and greenhouse gas emissions (GHG) reductions, these tools have been doing it for 67 years."

Johnson spoke as part of Cattlemen's College at the 2023 Cattle Industry Convention in New Orleans in February. ABB