

U.S. PIRG Comment on “Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed”

FDA Concept Paper Lacks Public Health Focus and Reasonable Timeline

Roughly two thirds of the medically important antibiotics sold in the United States go to [food producing animals](#).¹ Many of these critically important drugs are used to compensate for industrial farming practices that easily spread disease. This improper use of antibiotics can diminish their effectiveness and leave humans vulnerable to drug-resistant infections that can be [difficult, and sometimes impossible, to treat](#).²

About a [third of medically important antibiotics](#) approved for use in food animals via feed or water have no defined limit for how long they can be used, otherwise known as a “duration limit.”³ That means meat producers can dose herds of animals for several weeks, months or even indefinitely. Overusing antibiotics in this way can encourage antibiotic resistant bacteria to multiply and spread, and these “superbugs” can make their way off the farm and potentially infect people with dangerous illness. Duration limits are essential for reducing use of medically important antibiotics on farms and curbing antibiotic resistance.

Unfortunately, when it comes to slowing antibiotic resistance, the [concept paper](#) published by the FDA largely misses the mark.⁴

The objective, potential framework and recommendations laid out by the concept paper center around “optimizing dosage regimens” for use in livestock rather than ensuring medically important antibiotics stay effective for protecting human health.

The concept paper assumes that optimizing dosage regimens will decrease antimicrobial drug use on farms, thus reducing the risk of antibiotic resistance. While this may be true in some cases, the paper offers no guarantee for how the agency would ensure curbing antibiotic resistance is the top priority when setting duration limits. Instead, it allows drug manufacturers and veterinarians broad discretion to set these limits themselves.

Establishing duration limits on antibiotic use in animal agriculture is an essential response to a crisis that threatens to cause [10 million deaths](#) globally per year by 2050.⁵ Though we are critical in our comments, we applaud FDA for taking the time to draft this concept paper and make the following recommendations to ensure the draft guidance appropriately addresses antibiotic overuse:

1. The standards for maximum duration limits set by this concept paper are inconsistent with protecting public health. **The FDA should direct drug sponsors to label all medically important antibiotics with a specific maximum duration using the following considerations:**
 - i. 21 days or less should be the standard maximum duration for any use of medically important antibiotics in food animal production.
 - ii. Drug makers can apply for exceptions and establish a longer duration only if they can demonstrate that such use:
 - a. does not pose significant risk to human health by propagating antibiotic resistance; and
 - b. there are no readily available alternatives to this antibiotic use (ie. vaccination, improved feed quality, longer weaning periods, density management, etc.) that would achieve the desired outcomes

2. The timeline of this project is inconsistent with the urgent threat of antibiotic resistance. Under the projected timeline, drug company sponsors have at least six years to establish duration limits on their products, with an additional 3 years for generic versions of these medically important antibiotics to adopt the same recommendations. Including the time it will take for the final guidance to be issued by FDA, this process may not be complete until 2030.
The FDA should accelerate the timeline by:
 - i. Setting a deadline for establishing duration limits on all marketed products by the end of 2026;
 - ii. strongly encouraging pioneer sponsors to waive their 3-year exclusivity period; and
 - iii. adding enforcement language to the guidance if companies do not meet the projected timeline.

Additional recommendations:

- The FDA should consider recommending alternatives to antibiotics to prevent common livestock illnesses such as liver abscesses, bovine respiratory disease or aspergillus. Improved feed quality, improved sanitation standards and vaccination can decrease the likelihood of some of these common illnesses and reduce the need for antibiotics.
- The FDA should release a line item budget for its work on antibiotic resistance to show what resources it's dedicating, and what resources it still needs, to quickly execute the guidance on duration limits.

Without swift action to stop the overuse of antibiotics, we'll turn the clock back on modern medicine. We urge you to accelerate your timeline for establishing duration limits for all medically important antibiotics used in food animal production, and to ensure your top criteria in setting those standards is keeping antibiotics effective for human health.

Sincerely,

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Sources

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