

FDA Judicious Use Policy

On January 3, 2017, the Food and Drug Administration announced full implementation of its Judicious Use of Antibiotics policy, meaning medically important antibiotics used in food animals will be used only to fight disease under the guidance of a veterinarian.

Background: the Food and Drug Administration (FDA) approves antibiotics with four different label claims: Disease treatment, disease control, disease prevention and growth promotion. The first three are considered by FDA to be therapeutic—targeted at a specific disease or a specific disease-causing bacterium that is named on the label.

Label claims are different than routes of administration. Flocks and herds of food animals are typically administered medication in the feed. Antibiotics used to treat disease, for instance, are often administered in feed.

Medically important antibiotics are compounds— like penicillin or tetracycline— that are used in both human medicine and animal medicine. The full list is found in Appendix A of FDA’s Guidance for Industry #152.

FDA Action: In December, 2013, FDA released Guidance #209, describing how companies should remove growth promotion claims from medically important antibiotics and add veterinary supervision to the label. By April, 2014, ALL companies agreed to comply with the new FDA guidance. In addition to growth claims being removed, all remaining medically important antibiotics used in animal feed or water will require veterinary oversight. This will be accomplished by requiring veterinarians to provide a Veterinary Feed Directive (VFD) whenever antibiotics are used in food animals.

There are 287 products that have undergone a label change to comply with this policy. Results can be tracked here:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm>

The FDA announced on January 3, 2017 that this program has been fully implemented and all necessary label changes have been made.

Misconceptions:

1. FDA's plan is just voluntary and will not work as some companies will not comply.

The voluntary phase of this implementation is over. Companies were asked to voluntarily work with FDA in the agency's December 2013 announcement. By April 2014, all companies had made a commitment to do so, meaning they made a commitment to change the labels to comply with the FDA policy. Now that the label changes have been made, compliance is mandatory. It is illegal to use antibiotics for growth promotion. Veterinarians will write VFD's that authorize use according to the label, meaning for treatment, prevention or control. Use of antibiotics in feed or water that deviates from the label directions is strictly illegal.

2. There's a loophole that will allow farmers to continue using antibiotics to promote growth while calling it "prevention."

There are only six antibiotic compounds that currently have both a growth label and a prevention label. In each case, either the dose or duration of use—or both—is different for the growth and prevention uses. With the removal of the growth label at the end of 2016, only the disease prevention use, with a different dose or duration, will remain.

In general, prevention doses as approved by FDA are higher than growth uses. There is very little, if any, overlap between the two. Additionally, the legal prohibition against off-label use—or use that deviates from what is specified on the label—ensures that these antibiotics will not and cannot be used to promote growth.

3. This policy will fail because it won't reduce use of antibiotics.

The purpose of FDA's Judicious Use Policy is to promote the judicious use of important antibiotics to protect public health while ensuring that sick and at-risk animals receive the therapy they need. It is not known what effect it will have on total use. Total use is a function of many factors, including disease threats, weather and production levels. Furthermore, a large percentage of total use is with antibiotics that are not medically important and, therefore, not subject to this policy. The animal health and public health communities are united in support of funding requested by the President to enable USDA to do enhanced collection of data to better understand the uses of antibiotics.