



August 23, 2010

Division of Dockets Management (HFA305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

ATTN: Comment Docket No. FDA-2010-D-0094

To Whom It May Concern:

I am writing to you on behalf of Trust for America's Health, a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. We were pleased to see the Food and Drug Administration (FDA) release of draft *Guidance #209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*. We recognize that this is a pivotal first step in eliminating excess use of antimicrobials that are critical to protecting human health. However, the magnitude of the impending crisis posed by resistant organisms calls for a more comprehensive, legally-binding document.

TFAH strongly supports the need for regulations on the use of antimicrobial drugs for food-producing animals. The effectiveness of antimicrobial drugs in medical treatments has been threatened by the incidence of drug resistance; therefore, antimicrobial drug regulation in humans and animals should be of paramount concern for public health policy. As the Draft Guidance itself notes, numerous studies since 1969 have concluded that the use of subtherapeutic levels of antibiotics in food animals poses a significant risk to human and animal health. We fear that allowing this guidance to remain a voluntary policy will result in marginal, if any, reduction in injudicious use of antimicrobials. There will be little incentive for food producers to adjust their practices without the force of law. By issuing guidance now, we are concerned that it will be several more years before FDA is able to issue regulations over antimicrobial use in agriculture.

Recommendations:

In addition to issuing regulations, rather than guidance, TFAH recommends the following changes to the Draft Guidance:

- Clearly define judicious use, when antimicrobials are appropriate. These circumstances should be explicit, limited, and on a short-term basis. Specifically, we are concerned with the allowance for use for "prevention of disease" (p. 4, 16). Without defining what constitutes appropriate preventive use of antimicrobials, producers can continue to claim a preventive need for administering antibiotics to entire herds at a subtherapeutic level. Likewise, FDA

should define therapeutic and nontherapeutic (or subtherapeutic), to eliminate the opportunity for varying interpretations. Allowing these terms to be subject to industry reading will not achieve the Guidance's intended effect.

- Require veterinary prescriptions (or, as appropriate, Veterinary Feed Directive) for therapeutic provision of medically important antimicrobial drugs to food animals. In the U.S., humans require a prescription from their doctor to receive antibiotics. There is no reason why animal drugs should be treated differently, especially those that have such an impact on human health. We urge you to determine specific procedures by which antimicrobials could be used. We also recommend you revise the language to require direct veterinary oversight of the treated animal, rather than the current approach of allowing consultation with a veterinarian.
- Eliminate off-label use of antimicrobial animal products.
- Improve post-approval tracking. After policies are implemented, it is crucial the FDA monitor the use of medically important antimicrobials in agricultural settings.

The conclusion of this Draft Guidance notes that the FDA hopes to phase in measures to support its fundamental principles, "while minimizing adverse impacts on animal health and disruption to the animal agriculture industry." While this industry disruption should be a consideration, the utmost priority should be to protect public health. While this Draft Guidance is a significant step to addressing antimicrobial resistance, TFAH urges the Agency to take an even stronger stance on the issue. We hope that our comments will help the FDA in developing measures to do so.

Thank you very much for your consideration of this issue, and I hope that our input has been beneficial. If you have any questions, please do not hesitate to contact our Director of Government Relations, Annie Toro at (202) 223-9870 ext. 25, or via email at atoro@tfah.org.

Sincerely,

A handwritten signature in black ink that reads "Jeffrey Levi". The signature is written in a cursive, flowing style.

Jeffrey Levi, PhD
Executive Director