

March 10, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner
C/o Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

ATTN: Comments on Veterinary Feed Directive, Docket No.FDA-2010-N-0155

Dear Commissioner Hamburg:

On behalf of Trust for America's Health (TFAH), we are pleased to respond to the U.S. Food and Drug Administration (FDA) proposed rule language amending the Veterinary Feed Directive (VFD). The VFD is an important step in placing medically important antibiotics under veterinary supervisions when administered to large numbers of food animals. We believe veterinary oversight is a necessary step to help limit overuse of antibiotics in animal agriculture. However, we have several concerns with the proposed language.

As you know, bacteria resistant to antibiotics is a growing public health crisis, leading to at least 2 million antibiotic-resistant infections and 23,000 deaths per year in the United States.¹ Antibiotic resistance leads to more than eight million additional hospital days per year, costs the country an extra \$20 billion in direct healthcare costs and at least \$35 billion in lost productivity annually.² In its 2013 report on antimicrobial resistance, the Centers for Disease Control and Prevention (CDC) stated: "Because of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, not to promote growth."³ As such, FDA should ensure that the VFD will have a substantial impact on reducing the overuse of antibiotics in agriculture.

TFAH is concerned with several potential limitations in the proposed language:

- **Veterinary-Client-Patient Relationship:** We are concerned that the language within the proposed VFD would loosen existing requirements regarding the veterinary-client-patient relationship (VCPR). Current federal regulation requires a VFD be issued only within a valid VCPR, which requires the veterinarian to have recently seen the animals to be treated or visited the farm where they live. This ensures proper veterinary oversight of

¹ Centers for Disease Control and Prevention. *Antibiotic Resistance Threats in the United States*, 2013. Atlanta GA: CDC, 2013.

² The Cost of Antibiotic Resistance to U.S. Families and the Healthcare System. In *Alliance for the Prudent Use of Antibiotics*. Extrapolated from Roberts RR, Hota B, Ahmad I, et al. Hospital and Societal costs of antimicrobial-resistant infections in a Chicago teaching hospital: implications for antibiotic Stewardship. *Clin Infect Dis*, 15;49(8):1175-84, 2009.

³ CDC, *Antibiotic Resistance Threats in the United States*, 2013. p. 27.

administration of drugs impacting animal and human health. The proposed change would allow a VFD to be issued in the course of a veterinarian's professional practice, so any VCPR standard would now be left to the states. We are concerned that VCPR standards vary by state, and may or may not require direct knowledge of the animals and farm. FDA should restate the definition of a valid VCPR that is standard across states and involves the veterinarian's direct knowledge of the animals and farm. FDA should also clarify that veterinary oversight requires the veterinarian to have made a recent visit to the premise, not just the corporate operation, which may involve many different farms.

- **Record Keeping:** The proposed rule requires feed mills and veterinarians to keep records for only one year. We urge you to change this language to require copies of the VFD and other records for at least two years, as required in the existing regulation. Furthermore, FDA should require feed mills and veterinarians to submit each VFD to FDA for analysis and public reporting. We believe these changes are necessary to allow FDA to verify and investigate prescribing practices and to evaluate data to ensure that the proposed change is having a desired impact on the reduction of overall use of antibiotics in feed. One year of records, without proper transparency and evaluation, is inadequate to determine if feed practices are changing.
- **Expiration Date:** The proposed rule could allow the use of drugs long after the issuance of a VFD. As currently written, the proposed rule could allow for continuous use of an antibiotic for prevention purposes for many circumstances. We urge you to ensure that the expiration date of the VFD does not extend past the life of the targeted animals, six months after it is written, or the label directions—whichever is shortest. This provision will decrease the chances that antibiotics are reordered without a legitimate, identified need.

We urge FDA to make these changes and to issue, implement, and evaluate the VFD as quickly as possible.

Thank you for the opportunity to comment on this important proposed rule. TFAH is a nonprofit, nonpartisan public health organization dedicated to saving lives by making disease prevention a national priority. If you have any questions, please contact Becky Salay, TFAH's Director of Government Relations, at bsalay@tfah.org or 202-223-9870 ext. 15.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey Levi". The signature is fluid and cursive, with the first name "Jeffrey" being larger and more prominent than the last name "Levi".

Jeffrey Levi, PhD
Executive Director