

February 1, 2016

The Honorable Stephen Ostroff, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

RE: Docket No. FDA-2010-N-0155

Dear Acting Commissioner Ostroff:

The undersigned organizations appreciate this opportunity to comment upon [Draft Guidance for Industry #233 entitled “Veterinary Feed Directive Common Format Questions and Answers”](#) (the draft guidance). We believe that a well-designed common format for veterinary feed directives (VFDs) can help ensure that these drugs are used correctly and can also facilitate FDA’s ability to provide regulatory oversight on the use of VFD drugs.

We are concerned that the draft guidance does not adequately address the situation where a single drug is approved for multiple indications. All the examples provided in the draft guidance are for a single indication, but it is more common for feed applications to include multiple indications. While 2 of the 3 drugs currently approved as VFD do have only one indication per species, this is not the case for most of the medically important antibiotics in feed to be moved under VFD as [FDA’s judicious use plan](#) is implemented. FDA’s [list of applications affected by Guidance #213](#) includes 45 pioneer applications for use of medically important antimicrobials in feed. For 26 of these there are at least 3 separate indications for at least one of the approved animal species. For example, chlortetracycline ([NADA 046-699](#)) and oxytetracycline ([NADA 095-143](#)) each have over 4 indications for each of the major food animal species (chickens, turkeys, swine, and cattle) and tylosin ([NADA 012-491](#)) has 4 indications for use in swine. Among the drugs currently requiring a VFD, florfenicol ([NADA 141-246](#)) has multiple indications for use in finfish. For only 13 of the 45 pioneer feed applications affected by Guidance #213 are there just one indication for each approved species.

The VFD regulation ([21 CFR 558.6\(b\)\(3\)](#)) requires that the VFD drugs be issued for a single indication but the draft guidance never makes this clear and the examples in the appendices of the draft guidance provide a space for “indications” not a single indication. We ask that FDA clarify the guidance by explicitly requiring sponsors to include language directing the veterinarian to specify a single indication for which the VFD drug is to be used. The guidance should also include examples of a drug for which there are multiple indications per species and include language

directing the veterinarian to choose only one allowed indication. The VFD form developed by the sponsor of florfenicol for fish that is [available on line](#) directs the veterinarian to circle the species and indication. FDA could ask all sponsors to take a similar approach. Under the current situation where most medically important antibiotics used in feed are marketed over the counter, livestock producers have not had to choose among indications, so may be accustomed to using a single drug for multiple purposes at the same time. This guidance should require sponsors to develop forms that make clear that this is not allowed for drugs requiring a VFD.

The form should also make clear that for cases where a range of doses is allowed the veterinarian must choose a specific dose that is indicated on the form.

Thank you for your consideration and for the agency's continued commitment to addressing the public health threat of antibiotic resistance. We ask that you strengthen Guidance for Industry #233 by making it clear that a VFD can only be issued for a single indication with a specific dose.

Sincerely,

Keep Antibiotics Working

Food Animal Concerns Trust

Natural Resources Defense Council

Dignity Health

Michigan Antibiotic Resistance Reduction (MARR) Coalition

Center for Foodborne Illness Research & Prevention

Johns Hopkins Center for a Livable Future

Antibiotic Resistance Action Center at the Milken Institute School of Public Health, The George Washington University

School Food FOCUS

Food and Water Watch

Center for Food Safety

Consumer Federation of America

Society of Infectious Disease Pharmacists