August 1, 2013

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 Draft Codified Language for Docket No. FDA-2012-N-1046-0001

Dear Commissioner Hamburg:

We commend the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) for conducting public meetings to serve as listening tours regarding Draft Guidance for Industry #213 and the April 2012 notice of proposed changes to the Veterinary Feed Directive (VFD). Our written comments combine response to the documents as well as reaction to FDA remarks at the public meetings.

The VFD represents a viable method to allow antibiotics to be administered to large numbers of food animals at one time at the barn or pen level, for those few instances when such action would be warranted. The proposed draft language, along with full implementation of veterinary oversight sections of Guidance 213, would move many critically important antibiotics approved for over the counter sales to being under closer supervision by a veterinarian. We believe this is an important step to limit overuse of antibiotics in food animal production.

We remain highly concerned about the intended definitional change for the veterinary client patient relationship (VCPR), which would allow issuance of a VFD in the course of a veterinarian's practice, without necessarily requiring a visit to each facility. We agree that the VCPR can be supplemented by examination of health records, consultation, and epidemiology of disease, but it is not a substitute for timely veterinary visits. We instead urge the agency to retain the valid VCPR definition used in other FDA documents. That includes a requirement that a veterinarian has assumed the responsibility for making medical judgments on the animals, there is sufficient knowledge of the animals to initiate at least a general or preliminary diagnosis of the medical condition of the animals, and the veterinarian is readily available for follow-up. Such a relationship exists when the veterinarian has recently seen the animals or the premises where the animals are kept. We also have the added concern that FDA may consider the American Veterinary Medical Association recommendation to allow the definition of a valid VCPR to include knowledge of an operation without specific knowledge or visit to each facility.

At the public meetings it was made clear that FDA intends to allow a six month standing order or refills for drugs approved under the VFD process if there is no time frame in the drug application. The antibiotics currently available and approved for VFD use have no refills, but that was a decision by the drug sponsors and not by FDA. Several producer groups requested that

the default refill date be lengthened to twelve months, citing the time it currently takes to write a VFD. Since the revised regulations would streamline the VFD process and the intent is to increase veterinary oversight, six months is a reasonable time frame. A reevaluation of a facility's circumstances would be appropriate at least twice a year for determining if an antibiotic was still warranted and that other measures have been attempted to minimize the need for antibiotics in the feed.

The duration of use of an antibiotic in a herd, pen or barn was not addressed during the public meetings. The omission of any detail about this could allow for non-specified use of antibiotics over the lifetime of the animal, especially poultry and swine because of their shorter time to slaughter compared with beef cattle. We recommend the language be amended to include a defined duration of 21 days that is consistent with the current FDA Guidance for Industry #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern."

Removing the requirement that veterinarians specify the tonnage of feed and instead estimate the number of animals to be covered under the VFD is a sensible change that should streamline the VFD process. An estimate of animals to be treated is a more practical approach and more in line with a veterinary approach.

Stakeholder meetings also included discussion on allowing flexible dosing for antibiotics approved via the VFD process, meaning that veterinarians would have a legal and acceptable range of use that allows them to exercise their medical judgment in a given situation. Such flexibility has already been approved for two of the three existing VFD antibiotics, and use beyond this range is considered "extralabel" and disallowed. As FDA noted, to change dosing beyond what the drug sponsor chooses to request and is approved by FDA would require a Congressional change in the VFD law. Current flexible dosing practice provides adequate flexibility to address the realities of natural differences among animals and requires no further expansion or modifications in the proposed rule.

We urge FDA to finalize Guidance #213 with changes we have recommended earlier and issue a proposed rule regarding the VFD expeditiously with these recommendations included to create a more robust regulation that protects human health by providing more veterinary oversight of antibiotic use in food animal production. We look forward to continued dialogue with FDA, USDA, and interested parties on these important issues.

Thank you for your consideration.

Sincerely,

Alliance for the Prudent Use of Antibiotics
Center for Food Safety
Food Animal Concerns Trust
Health Care Without Harm
The Humane Society Veterinary Medical Association
Keep Antibiotics Working

Natural Resources Defense Council
Pediatric Infectious Diseases Society
The Pew Charitable Trusts
The Society of Infectious Disease Pharmacists
Trust for America's Health