ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

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Division of Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2010–N–0155; Veterinary Feed Directive; Draft Text for Proposed Regulation

The Animal Health Institute (AHI) submits these comments to Docket No. FDA–2010–N–0155, "Veterinary Feed Directive; Draft Text for Proposed Regulation." AHI is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

AHI appreciates the approach the agency has taken in developing the proposed changes to the existing VFD regulation by soliciting wide stakeholder input on how the rule can better serve the needs of the animal drug industry, veterinarians, producers, and feed manufacturers while assuring these products are being used safely. We are pleased that FDA has taken many of these concerns into consideration in the draft text. These changes are critical to the efficient operation of the program, if as expected, the labeling of many currently approved feed and water administered antibiotics is changed from over the counter status to VFD only.

While we overall strongly support the new language, we do have some specific comments on the new text:

- Paragraph 558.6 (b) (2) (viii) - <u>The approximate number of animals to be fed the medicated feed prior to the expiration date on the VFD</u>;

    - This requirement would be difficult to meet if the veterinarian authorizes multiple refills of the drug during the expiration date of the VFD and there are several facilities within the specific geographical location where the VFD drug is being ordered. It would be preferable to revise this provision to only require an estimation of the number of animals to be treated in the original order since not all animals initially treated may require re-treatment.

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- Paragraph 558.6 (b) (2) (xii) – <u>The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing</u>;

    - This provision is not relevant to currently approved indications on medicated feed products and would severely limit the ability of the veterinarian to adequately treat animals under his care. Since refills were not considered a condition of use when these products were initially approved, a veterinarian would be precluded from advising the producer on follow up treatment if needed. We suggest changing the wording from, "*…if **permitted** by the drug approval,…*" to "*…if **specified** in the drug approval…*" in order to provide the necessary flexibility in using these products.

AHI thanks the agency for publishing this draft text as a prelude to a proposed rule.

Thank you in advance for your consideration of these comments. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,

Richard A. Carnevale, VMD