KEEP ANTIBIOTICS WORKING
The Campaign to End Antibiotic Overuse
www.KeepAntibioticsWorking.com

August 24, 2010

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

Re: Advanced Notice of Proposed Rulemaking on Veterinary Feed Directive
Docket No. FDA–2010–N–0155—0014

Keep Antibiotics Working (www.KeepAntibioticsWorking.com) is a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in farm animals. On behalf of the more than 11 million members of these groups, Keep Antibiotics Working (KAW) appreciates this opportunity to submit comments on the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking (ANPR) regarding potential changes to its current regulation relating to veterinary feed directive (VFD) drugs, 75 *Fed. Reg*., 15387-88 (March 29, 2010).

In March 2010, the FDA issued an ANPR to solicit comments from the public on potential changes to improve the efficiency of the Veterinary Feed Directive (VFD) program. The VFD program covers drugs, including antibiotics, which must be administered under a veterinarian's order and professional supervision. The agency is seeking comment on all aspects of the VFD regulation, but particularly those related to efficiency, to help in drafting a proposed rule in the near future.

Background

KAW is deeply disappointed in what the FDA is considering to do with this ANPR. We are also disappointed in the agency's overall lackluster response to the threat of antibiotic resistant human infections stemming from the use of medically important antibiotics in food animals.

In its ANPR on VFD, the FDA suggests: (i) it will rely on phased-in voluntary reductions in the use of medically important antibiotics for food animals; and (ii) it will relax the current regulations of such antibiotics with veterinary feed directive use.

Meanwhile, the FDA has: (iii) failed to revoke the non-therapeutic use of penicillin in animal feed even though it first proposed such a revocation in 1977, and told Congress in September 2008 that it had completed its review of the scientific literature and was still concerned about such use; and (iv) failed to ban the extra-label use of cephalosporins in

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food animals even though it proposed doing so in June 2008 as evidence showed that this use contributed to serious resistant infections in human.[1]
Having commented within the last year on FDA's inaction *vis-a-vis* (iii) and (iv) above, KAW now offers these written comments on the FDA's proposed steps (ii) and will comment on (i) under the appropriate docket.

Comments
KAW supports the concept that certain drugs should only be made available under Veterinary Feed Directive orders or prescriptions and that the process for issuing the VFD orders should be as efficient as possible. We note that recent FDA guidance clarifying how VFD orders could be submitted electronically is an appropriate move in that direction and we support that action.

However, KAW is perplexed and troubled that solicitation of comments on the efficiency of the VFD program is the first concrete step by the FDA under the current administration to address how antimicrobials are used in food producing animals. Streamlining the VFD is a misguided use of agency resources. For over thirty years, FDA has been discussing the need to address the overuse of antimicrobials in food producing animals. The agency should be attacking the problem of overuse. Instead, the agency now has decided to begin a multi-year rulemaking process aimed at making it easier to use certain antimicrobials in feed.

KAW is concerned that FDA will go beyond streamlining the process of issuing orders and will reduce the already minimal requirements for veterinary oversight that require a valid veterinarian-client-patient relationship (VCPR) before issuing VFD orders. Those requirements set out in the Code of Federal Regulations (21CFR 530.3) are as follows:

> (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
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> (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
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> (3) The practicing veterinarian is readily available for follow up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

KAW believes these three requirements are needed to ensure that the veterinarian will have adequate information to determine appropriate antimicrobial therapy when needed.

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[1] KAW's November 2009 letter to the FDA on cephalosporins is available here: http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=106980. KAW's May 2010 letter to the FDA on penicillin is available here: http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=107518.

The FDA has recently described in Draft Guidance #209 five factors to consider when determining appropriate antimicrobial use. Weakening any of the three requirements above would make it unlikely that a veterinarian would have adequate information to consider these five factors.

For these reasons, although KAW supports efficient administration of VFDs, it does not support a weakening of the core VFD regulation and does not believe that regulatory change is needed. However, if the FDA determines that changes are to be made to these requirements, then any changes must be explicitly designed to protect public health and to make sure that antibiotics are used only when needed. If FDA moves forward with rulemaking, KAW has strong recommendations on what sort of changes could provide greater efficiency without weakening the protections built into the VFD. We would request an opportunity to share those recommendations with the agency.

KAW believes the FDA should avoid spending the considerable resources that would be required to rework the VFD regulations. We urge the FDA to instead focus on taking concrete steps to reduce the inappropriate use of antimicrobials in food producing animals. Numerous actions -- such as creating VFD regulations, allowing extralabel drug use in animals, and creating incentives for the development of drugs for minor uses and minor species – already have been taken over the last 30 years to make sure that there are adequate drugs available to treat sick animals.

KAW does not favor going ahead with a streamlining or relaxation of the VFD regulations at this time. If the agency proceeds with such actions, it should only be as a part of a well- articulated plan leading to the reduction in antibiotic use. Now is the time for FDA to take action to protect public health by curbing the continued inappropriate use of antimicrobials in food producing animals.

Sincerely,

Richard R. Wood
Chair, KAW Steering Committee