KEEP ANTIBIOTICS WORKING

The Campaign to End Antibiotic Overuse

www.KeepAntibioticsWorking.com

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Michael R. Taylor, J.D.
Deputy Commissioner for Foods and Veterinary Medicine
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Deputy Commissioner Taylor:

We, the members of the Keep Antibiotics Working (KAW) coalition, want to thank you for meeting with us on July 2nd to discuss the important public health issues prompted by our discovery that Novartis, an animal drug manufacturer, was promoting an extra-label growth claim for one of its animal drugs on its website. We notified you about the Novartis promotional material in a letter sent on May 14, 2014. KAW is concerned that many animal drug companies will adopt this strategy of advertising and promoting illegal growth promotion uses of drugs as a tactic to maintain their sales of medically important antibiotics for food animals, even as they voluntarily: (a) move from over-the-counter (OTC) status of these drugs to either prescription status or veterinary feed directive (VFD) status, and (b) remove growth promotion claims from the drug label.

We believe that addressing this marketing strategy and the broader issue of the continued overuse of antibiotics for routine disease prevention and control, is central to the success of FDA's efforts to address antimicrobial resistance. If FDA's assumption is correct, that eliminating labels for growth promotion can reduce antibiotic use, then the lack of a clear distinction between the uses FDA is trying to eliminate and those that FDA deems acceptable will hinder that reduction. Novartis' promotional materials are intended to blur the distinction between growth promotion and other antibiotic uses and encourage swine farms broadly to purchase and use these antibiotics for purposes including growth promotion.

Allowing this type of marketing can only hinder FDA's animal drug policy as this type of marketing promotes the continued inappropriate use of antibiotics. Unless FDA is willing to tackle inappropriate uses for prevention and control, including prohibiting this type of advertising, the high rates of antibiotic use and the resistance associated with such use will not be curbed. In this case, the Agency will have wasted the considerable resources it has invested in encouraging drug label changes.

An approach similar to FDA's plan of prohibiting antibiotics for growth promotion and requiring veterinary oversight was tried previously in the Netherlands and did not result in reductions in antibiotic use. The Netherlands responded to the failure of the growth promotion ban by taking additional steps including the creation of specific targets for reductions in antibiotic use to be met over a set timeline and the prohibition of the use of antibiotics for disease prevention. In this way, they were able to significantly reduce antibiotic use in food animal production. The Netherlands also monitors how antibiotics are used, which is essential to understanding the impacts of its antibiotic reduction efforts. We urge the FDA to take similar actions to supplement the labels changes recommended by FDA's current plan.

We were dismayed by Dr. William Flynn's comments in our July 2nd meeting indicating that he understood how Novartis's promotional materials could lead to public misunderstanding of the impacts of the FDA's policy, but he did not seem concerned that it would lead to continued inappropriate use. In our view the problem is not that companies don't *appear to be* reducing use, but the fact that they *are not* doing so. We believe that this and other strategies to keep sales up while technically complying with the policy will undermine a successful reduction of antibiotic use, and ultimately resistance.

We are further concerned by the apparent reluctance of the CVM staff to embrace reductions in antibiotic use as the most appropriate intermediate measure of the voluntary plan's effectiveness. This reluctance is reflected in its policies. As we have detailed in comments to the FDA, the proposed changes to the Veterinary Feed Directive (VFD) rule seem to be designed to ensure that antibiotic use will be able to continue unchanged once drugs are moved under VFD, an outcome inconsistent with a plan aimed at reducing antibiotic overuse.

We urge FDA to explicitly acknowledge that reduced use is a practical goal of its policy and then take steps to close the gaps in its approach to addressing antibiotic resistance that contribute to continued overuse. If, indeed, the CVM would be satisfied with changing labels without reducing use, we fear that the end result will be no significant change in antibiotic use and ultimately in antibiotic resistance. At our meeting, CVM staff said that the advertising of extra-label uses of animal drugs had gone on for many years and that FDA's current set of regulations is adequate to enforce FDA's extra-label advertising policies.

So that we may better understand the Agency's current position on advertising, we request that you supply us with information on the instances since January 1, 2010, where FDA asked an animal drug company to change its advertising or promotion of an extra-label use of an animal drug, including: (1) the approximate date on which the FDA first expressed its concerns to the company; (2) whether the drug was OTC, prescription, or VFD; (3) the type of animal (such as swine or cats) for which the drug was intended; and, (4) the extra-label claim that the FDA was concerned about. If the FDA ultimately sent a letter to the company, please supply a

copy of the letter or any informal communications from the Agency's to the company. Please also let us know the company's response to FDA's communications, and if the company failed to comply with FDA requests, the action taken by FDA (such as referring the advertisement to the Federal Trade Commission).

It has been more than two months since KAW notified FDA about Novartis's objectionable promotional materials yet the company's website still includes the materials, albeit in a slightly modified form. Novartis continues to promote the growth promoting benefits of the drug's use. Please inform us of the additional steps, if any, FDA intends to take with Novartis and how the Agency intends to address similar promotional materials coming from other companies.

We appreciate your taking the time to meet with us on the promotional claims for extra-label and illegal uses of animal drugs. It is an issue with important ramifications for the success of FDA's voluntary program to control the overuse of animal antibiotics.

Sincerely,

Steven Roach
Food Safety Program Director
Food Animal Concerns Trust
Keep Antibiotics Working Member Organization

CC (by email): CVM Director Dunham, CVM Deputy Director Forfa, CVM Deputy Director for Science Policy Flynn

Hyperlinks for print version in order occurring in document:

http://www.keepantibioticsworking.com/new/Library/UploadedFiles/KAW%20letter%20on%20drug%20promotion.pdf

http://www.government.nl/documents-and-publications/leaflets/2014/02/28/reduced-and-responsible-use-of-antibiotics-in-food-producing-animals-in-the-netherlands.html

http://www.us.denagard.com/product-information/grow-finish.htm