

KEEP ANTIBIOTICS WORKING

The Campaign to End Antibiotic Overuse

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STEERING COMMITTEE

Center for Science in the
Public Interest

Environmental Defense

Food Animal Concerns
Trust

Global Resource Action
Center for the Environment

Humane Society of the
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Sierra Club

Union of Concerned
Scientists

Waterkeeper Alliance

October 24, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane,
Rockville MD 20857-0001

Dear Acting Commissioner von Eschenbach,

I write on behalf of Keep Antibiotics Working (KAW), a coalition of health, consumer, agricultural, environmental, humane, and other advocacy groups with more than nine million members working to protect public health through the promotion of the responsible use of antibiotics in animal agriculture. Food Animal Concerns Trust (FACT) and the Union of Concerned Scientists (UCS), which were represented at a Veterinary Medicine Advisory Committee (VMAC) meeting held September 25, 2006, are KAW member organizations.

KAW is writing out of concern that the FDA's Center for Veterinary Medicine (CVM) might disregard the recommendation of the VMAC and approve cefquinome, a fourth-generation cephalosporin, for use in animal agriculture. In our view, such an approval would be a big step backward for the public health. Fourth-generation cephalosporins are highly valued in human medicine as treatments for serious and life-threatening infections. Widespread use of these drugs in cattle could elicit resistant pathogens impervious to the drugs, undercutting their efficacy in human medicine.

We are specifically requesting that your office ensure that the CVM adheres to the FDA regulations requiring that the VMAC's finding be accurately characterized in the report submitted by the VMAC to the FDA on the fourth-generation cephalosporin application.

On September 25, a majority of the VMAC found that the risk assessment prepared by Intervet, the sponsor of the application to use two formulations of fourth-generation cephalosporins in cattle, did *not* demonstrate that the cefquinome is safe with respect to the potential for transfer of antimicrobial resistant organisms to humans. This finding strongly supports disapproval of the current application to use these drugs in cattle. The arguments are even stronger in light of the likelihood that the drug would be approved without strong prohibitions on extra-label use and thus would be used in other food animals, including swine and poultry.

PO Box 14590 • Chicago, IL 60614-0590

PHONE: 773-525-4952 • FAX: 773-525-5226 • E-MAIL: information@KeepAntibioticsWorking.com

We are concerned that the CVM might mischaracterize the finding in a way that would facilitate the approval of the drug. Concerns about the characterization of the finding of VMAC committees have arisen before in connection with the VMAC meeting on Tulathromycin held in the fall of 2004. The committee chair's "meeting minutes summary" for that meeting states, "The majority opinion of the committee was that the risk management recommendations brought before the committee were adequate. The majority stated extra-label use should not be allowed for food-producing species other than those approved in the labeling; however, there were several qualifications of this answer." This statement appears to be internally contradictory. Because most VMAC members expressed the need for an extra-label use restriction pertaining to other species, they necessarily did not agree with the risk management recommendations, which did not include any extra-label use restriction. This problem might have been caught and corrected if the minutes had been circulated to committee members for their approval as is required by law.

The public expects, and the law requires, that advisory committee records accurately reflect the events of the day and the substance of the committee's deliberations.

To be specific, regulations governing FDA advisory committees require that FDA keep "detailed minutes" of the committee meetings. 21 C.F.R.14.60(a). The minutes must include "a complete and accurate description of matters discussed and conclusions reached." 21 C.F.R. 14.60(b)(4). The accuracy of the minutes must be "approved by the committee and certified by the chairman." 21 C.F.R. 14.60(a).

The regulations also state: "Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee. It is the responsibility of each committee member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting the committee member attended." 21 C.F.R. 14.22(i)(4). This means, for example, that a report prepared by the Chair of the VMAC would have no status as part of the meeting records unless officially approved by the committee.

We urge you to make sure that the FDA complies with these requirements by circulating any minutes and/or reports of the September 25 VMAC meeting to each member of the committee for their approval prior to certification by the chair.

The FDA's handling of scientific advice is under increasing public scrutiny, with critics alleging that the agency sometimes gives industry or ideological interests priority over science and the public health. A decision by the FDA to disregard the VMAC's advice on fourth-generation cephalosporins would fuel those concerns.

KAW urges the FDA to follow its regulations and ensure that the report issued by the VMAC on fourth-generation cephalosporins accurately reflects the committee's

deliberations and intentions. Once the report is issued, we urge the FDA to implement the VMAC's advice and deny the application of product formulations based on fourth-generation cephalosporins for use in animal agriculture.

Thank you in advance for your thoughtful consideration of this pressing public health matter.

Sincerely,



Richard Wood
Steering Committee Chairman
Keep Antibiotics Working

cc:

Stephen F. Sundlof, D.V.M., Ph.D.
Aleta Sindelar, R.N.
Arthur L. Craigmill, Ph.D.
Corrie Brown, D.V.M., Ph.D.
Gregory Jaffe, Esq.
Sherman (Skip) W. Jack, D.V.M., Ph.D.
John J. McGlone, Ph.D.
Mark G. Papich, D.V.M.
Richard A. Sams, Ph.D.
Sam Groseclose, D.V.M., MPH
Gatz Riddell, D.V.M.
John R. Glisson, D.V.M., MAM, Ph.D.
James E. Leggett, Jr., M.D.
L. Barth Reller, M.D., D.T.M.&H.