KEEP ANTIBIOTICS WORKING

The Campaign to End Antibiotic Overuse

www.KeepAntibioticsWorking.com

February 16, 2009

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

On behalf of Keep Antibiotics Working (KAW), I write to express our concern about the approach being taken by the Food and Drug Administration (FDA) to address the non-therapeutic use of antimicrobial drugs in food-producing animals. KAW is a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups working to protect the efficacy of antibiotics in both human and veterinary medicine.

We applaud the FDA for identifying the need for federal action in the first place. However, we believe the proposed approach is incomplete, and could be significantly strengthened so as to have the desired outcome of reducing antimicrobial resistance.

Our understanding from conversations with FDA staff and from FDA's public statements is that the FDA is asking drug manufacturers to voluntarily withdraw growth and efficiency claims for antimicrobials, and to voluntarily modify all other claims so that they can be used only under veterinary oversight. KAW believes that this approach may require considerable effort on the part of FDA while having very little impact on public health.

First, for this approach to have a public health impact it must lead to a reduction in the use of antimicrobials in food producing animals. The reduction of actual use, not just changing how use is described, would negatively impact the manufacturers' profitability so it is unrealistic to expect them to voluntarily make the change. There may be some public perception benefits and the potential for marketing new non-antimicrobial products, but there is little evidence that companies believe these benefits would be sufficient to offset the loss of sales.

KAW is concerned that the FDA, in attempting to gain industry acceptance of its plan, may make changes that allow for greater antimicrobial use such as modifying requirements for using veterinary feed directive antimicrobials, without ever achieving

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any significant restriction in label claims. In short, we consider it unlikely that animal drug manufacturers will voluntarily take more than cosmetic actions unless the FDA requires drug manufacturers to show that existing non-therapeutic approvals meet current safety standards as described in Guidance for Industry #152.

Second, even if the FDA's approach as we understand it were to gain industry acceptance, it is still an incomplete response because there is considerable overlap between growth/efficiency approvals and disease prevention approvals. Withdrawing approvals for the economic use of antibiotics as growth promoters may have a very limited effect because growth and efficiency claims are only a small part of non-therapeutic use.

KAW has examined label claims for growth promotion and feed efficiency to understand the impact of a ban on just growth promoters by using indications codified in the federal register.[1] Our analysis is contained in the attachment. The analysis strongly suggests the following:

1. A growth promoter ban will have little if any impact because most antibiotics approved for growth promotion are also approved for disease prevention – typically at even higher usage levels. In fact our analysis could identify only three situations (among those we examined) where this was not the case.[2]

2. Because of the large overlap between growth promotion and disease prevention claims on labels, producers may continue using drugs labeled for disease prevention for economic - not animal health - reasons. The net result in that case would be no change in antimicrobial use. Where the labeled prevention dose is higher, the net result actually could be an increase in the amounts of antimicrobials used in feed.

KAW is concerned that focusing withdrawal efforts on growth promoters alone also will undermine the FDA's policy of making decisions on drug safety independently of potential benefits to drug users. The requirement that drugs be shown to be safe is the primary purpose of drug licensing in the U.S. If the FDA determines that a drug used for growth promotion at a specific dose and duration is unsafe, then the same drug at the same dose and duration for disease prevention will be equally unsafe. The intent of the user has no bearing on the safety of the drug. Guidance 152 includes extent of use considerations, such as duration and number of animals treated, but does not consider intent of use in its risk management recommendations.

[1] We did not include all the drug combinations. For example, there are some sulfonamides that are licensed in combination with roxarsone for coccidiosis prevention and growth. Without growth they are licensed only for prevention and so we considered the growth part was linked to roxarsone.

[2] The three cases are sulfonamide approval in feed for cattle, penicillin in feed for chickens and turkeys, and streptogramin in feed for turkeys. For macrolides, oleandomycin and erythromycin could no longer be used in feed, but tylosin would still be available for prevention.

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Keep Antibiotics Working fully supports FDA's determination to address the sources of antimicrobial resistance from food animal origin. We also look forward to discussing with you federal responses that would result in the desired outcome of protecting public health. We thank you for the leadership you are providing on this important issue.

Sincerely,

Richard R. Wood
Chair, Keep Antibiotics Working Steering Committee

cc: Dr. Joshua Sharfstein, Principal Deputy Commissioner, FDA
Michael Taylor, Esq., Deputy Commissioner, Office of Foods
Dr. Bernadette Dunham, Director, FDA Center for Veterinary Medicine
The Honorable Louise Slaughter, Member of Congress

Attached: Growth Promoter Only Ban Analysis

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