MEETING WITH CONSUMER GROUPS
6/13/01

Participants

FDA/CVM:

Dr. Stephen Sundlof, Director
Dr. Linda Tollefson, Deputy Director
Dr. Bert Mitchell, Associate Director for Policy and Regulations
Dr. Dan McChesney, Acting Director, Office of Surveillance and Compliance
Dr. Bill Flynn, Temporary Assignment, Office of the Director
Mrs. Linda Grassie, Deputy Director, Communications Staff

Dr. Richard Wood, Food Animal Concerns Trust (FACT)
Karen Florini, Environmental Defense
Terri Stiffler, Environmental Defense
Dr. Margaret Mellon, Union of Concerned Scientists
Tamar Barlam MD, Center for Science in the Public Interest
Dr. Suzanne T. Millman, Humane Society
Dr. David Wallinga, Institute for Agriculture and Trade Policy

Background

Dr. Richard Wood requested this meeting as a follow-up to meeting the groups had with the Center in October 2000.

Discussion

Status of the NOOH to withdraw the approval of a fluoroquinolone drug used for poultry

Dr. Tollefson explained that CVM was reviewing the voluminous response from Bayer Animal Health to the NOOH. If CVM decides that a hearing on this proposed withdrawal of approval for Baytril in poultry is justified, the Center will send a recommendation to the FDA Commissioner. Included in this recommendation will be the basis for the recommendation (specific issues to be discussed.) If the Commissioner agrees, he or she will appoint a group to handle the hearing (separation of function), and ask the FDA Administrative Law Judge to schedule the hearing. The Center will assist in resolving the issue.

The consumer participants were concerned about the length of time it might take to hold a hearing, have a decision, etc. Dr. Tollefson explained that this was basically out of the Center's hands once a recommendation was made. But, she said that she believed that it was likely that a hearing would not be held for at least one year.

The consumer groups were also concerned that a new Commissioner might not be supportive of CVM's case, but Drs. Sundlof and Tollefson said that they believe we have a very good scientific case for withdrawing the approval of this product.

The consumer groups said that they are looking for ways that they can participate in the hearing and the effort to have the product withdrawn from the market. They mentioned that some of them had retained the legal services of Bill Schultz (former FDA employee), and that they were considering filing a motion in support of the withdrawal.

Discussion of the need to have better data on the quantity of antimicrobial drugs used in food-producing animals

CVM officials said that we are working on these proposed regulations that would give the Agency authority to request more detailed data on the sales of veterinary antimicrobials. This data would be required from the drug manufacturers.

The consumer groups said that they plan to meet with OMB and possibly HHS before these proposed regulations publish. They want to make sure that their strong support for collecting this data is known.

FDA response to a Citizens Petition from the groups to ban the use of medically important antimicrobials for growth promotion in food animals

The consumer groups were concerned that the response essentially said that each antimicrobial would need to be reviewed separately, rather as a group. The consumer representatives shared their view that subtherapeutic uses of antimicrobials were the most important. Dr. Sundlof said that the Center's view was that we should look at the drugs of most importance first -- as articulated in our Framework document. He pointed out that we started with a therapeutic drug (fluoroquinolone for poultry) and now are doing a risk assessment on a drug mostly used subtherapeutically (virginiamycin.)

Dr. Tollefson pointed out that under the law, we must be able to associate harm to a particular drug used in animals. It is not sufficient to establish that there is resistance to a drug (such as tetracycline,) unless we can also establish that the resistance is related to use in animals.

The consumer groups said that they are not satisfied with the Agency's definition of "no harm." They plan to develop strategies to change the use of antibiotics in agriculture. They plan to develop public information campaigns to increase public awareness of this issue. The groups also said that they would be interested in having separate meetings with CVM concerning the Framework document. Dr. Flynn agreed to work with them to hold such meetings.

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