



AMERICAN ASSOCIATION OF SWINE PRACTITIONERS

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October 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 98D-0969

Dear Sir or Madam:

The American Association of Swine Practitioners is submitting comment in response to the general public meeting that was held on October 4, 1999 and to the further planning of the upcoming public workshops related to antimicrobial resistance and the proposed framework.

We agree with the FDA that it is essential to provide opportunities for public input regarding the public workshops. Meaningful public input is needed. Given the format and outcome of the recent public meeting, it might seem that FDA has already moved well beyond the input stage of the planning process. We are hopeful that is not the case since it would indicate that the FDA is only cognizant of meeting its legal requirements and maintaining the appearance of seeking input. We are optimistic that the Agency will choose to dispel this perception and commit to a workshop process that will result in substantive input.

The general public meeting was extremely limiting. The FDA gave participants little, if any, specific issues on which to comment. Therefore, most of the comments were general in nature and contained most of the rhetoric heard at previous meetings. To our knowledge, nothing new or innovative came out of this meeting. If the FDA truly wanted input, it would have been advantageous to publish specific issues and plans prior to the meeting. It is extremely difficult to comment on plans or agendas until the specifics of those are known. In addition, the time allotted for comment and ensuing discussion was unacceptable for those wishing to generate any new ideas for the planning process for these two workshops.

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The AASP urges the FDA to reconsider its process for seeking input into risk assessment/thresholds and pre-approval studies. These are critical areas of the framework and antimicrobial resistance. They have huge implications for the future of animal drug availability and animal agriculture. We cannot afford mere “window dressing” to replace open and meaningful dialogue between stakeholders and the Agency.

Substantive input requires that interested stakeholders have prior access to the specifics of the issues, as well as the specific questions that are to be addressed in a workshop. Also required is the time necessary to consult with experts and constituents before formulating science-based comment. Specifically, the release of the FDA’s risk assessment just days before the planned workshop does not promote nor encourage meaningful input. Fortunately, there are at least two models that have been successfully used for seeking substantive input.

The FDA has previous experience in seeking meaningful input through the process of bringing the veterinary feed directive to fruition. It was that process that allowed all stakeholders ample opportunity to prepare and deliver input to the Agency, as well as openly discuss and debate points of contention among themselves. The result was the enactment of policy that was accepted by the involved stakeholders as well as the FDA.

Another precedent for seeking meaningful input was accomplished by the US Department of Agriculture (USDA) through a round table process during the development of the HAACP system. This process was extremely successful in structuring the sought-after input. It provided background material on the specific issues. It detailed specific questions to be addressed during the process. In the words of the USDA’s Food Safety Inspection Service, it was viewed “as an opportunity to allow free and frank discussion of the legitimate concerns of all constituents prior to the issuance of a proposed regulation”. The magnitude of the issue of developing HAACP relates well with the magnitude of the antimicrobial resistance issues confronting the FDA. Both are complex and daunting in depth and breadth.

There is a world of difference between merely doing things right and doing the right thing. An input process whose main goal is window dressing will do nothing to protect the health of humans or animals. There have been a myriad of scientific opinions offered on the hazard of antimicrobial resistance. They seem to agree that there is no imminent risk to public health due to use of antimicrobials in food animals. The stakes are too great to fall back to a position based on politics rather than one based on science.

The AASP urges the FDA to use due caution in proceeding with the framework without meaningful input from the affected stakeholders. There is no need for the Agency to set short and unrealistic timelines for the workshops since the proposed framework currently has no legal standing and no regulatory deadlines. As stated before, the release of the FDA’s risk assessment just days before the planned workshop does not promote nor encourage meaningful input. We urge the FDA to either release the risk assessment several weeks prior to the workshop or to postpone the workshop.

The AASP is willing to assist the FDA in reaching meaningful scientific consensus on the issues surrounding the proposed framework and antimicrobial resistance. Thank you for this opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "Tom Burkgren". The signature is written in black ink and has a fluid, connected style.

Tom Burkgren, DVM, MBA
Executive Director



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