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October 22, 1999

Dr. Stephen Sundlof
Director, Center for Veterinary Medicine
Food and Drug Administration
Mail Code HFV-1
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

As the date for the Workshop on Risk Assessment and the Establishment of Resistance Thresholds approaches, we are becoming concerned that the FDA-commissioned risk assessment on *Campylobacter*-Poultry-Fluoroquinolones has not been made available for review. We are especially concerned with the public announcement that the risk assessment will not be available until the end of November.

The stated purpose of the workshop is to discuss the CVM's risk assessment model to evaluate the risk to human health from resistant foodborne pathogens associated with the use of antimicrobials in food-producing animals. The meeting will also discuss the Center's current thinking on the use of this model to establish resistance and monitoring thresholds in food-producing animals. To enable an intelligent discussion of these extremely important topics, all stakeholders need more than the anticipated 10 days to study the model in preparation for the meeting. These critical topics should not be rushed just to meet an internally established timeline.

It is also necessary that the agency ensure that all scientific references used in the development of the model are available for review in conjunction with the model. This request specifically includes the CDC *Campylobacter* case-control study which has not yet been published.

We urge the agency to provide at least one month for review of the model and references before the workshop is conducted. If necessary, the workshop should be postponed.

Sincerely,

Bruce W. Little, DVM
Executive Vice President

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SCIENTIFIC ACTIVITIES DIV.

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