



DELMARVA POULTRY INDUSTRY, INC.

R.D. 6, BOX 47, GEORGETOWN, DELAWARE 19947-9575 • PHONE: 302/856-9037 • FAX: 302/856-1845 • E-MAIL: DPI@CE.NET

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Dr. Margaret Miller
HFV-1, Room 482
FDA, Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Dear Dr. Miller:

I am writing to you on behalf of Delmarva Poultry Industry, Inc. (DPI), the 4,000 member trade association working for the continued progress of the broiler chicken industry in Delaware, Maryland, and Virginia.

DPI has serious concerns about the "Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals." The framework reaches a conclusion not supported by numerous scientific bodies studying the available evidence and data. The only way to develop a sound policy to address the concern of antibiotic resistance is to conduct a comprehensive risk assessment. Without such an assessment, FDA will have difficulty convincing persons that the framework is risk-based and will address the real resistance issues. Many scientists place great significance on the pending risk assessment study at Georgetown University and yet you initiate this new framework without waiting for the results of that study.

FDA is preparing to implement a document that will reduce the availability of antimicrobials without necessarily reducing resistance. Additionally AVMA is developing its "judicious use guidelines" which can probably accomplish some of the intentions of the framework. Again, why rush when the science is still unclear?

This proposal will virtually eliminate new drug development for food animal medicine without correcting the specified problem-increased bacterial resistance in human medicine. I say this because the proposal in no way modifies drug usage either in human medicine or in nonfood-animal medicine. It is very difficult to believe that all "the problem" comes from antibacterial drug usage in food animal medicine.

The framework calls for on farm post-approval monitoring programs, which raises even more concern. What are the resistance thresholds for each drug that would prompt concern? If these are not known, who will define them? Currently, manufacturers of certain pharmaceuticals are being required to develop PAMP for

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their products. Would these data be used to calculate resistance thresholds or would more studies be required? On farm work means more people coming on the farm. We are concerned animal about disease biosecurity issues.

While we recognize the concern about antimicrobial drug resistance, we really wonder if this framework document does not represent a hasty action which may not even reach the target. We also wonder if anyone has given serious consideration to the potential impact of less availability of antimicrobial drugs in food producing animals on the microbial load carried by those animals.

Sincerely,

A handwritten signature in black ink that reads "Bill Satterfield". The signature is written in a cursive, slightly slanted style.

Bill Satterfield
Executive Director

BS:sb
b\DrMiller.ltr