

WOODRUFF & HOWE
ENVIRONMENTAL ENGINEERING, INC.

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July 1, 2004

Dr. Lester Crawford, Acting Director
Food and Drug Administration
5600 Fishers Lane, Room 1471
Mail Stop HF-1
Rockville, Maryland 20857

Dear Dr. Crawford:

I am submitting this letter in support of Bayer's defense of the continued therapeutic use of Baytril for broilers and turkeys. I, on behalf of my company Woodruff & Howe Environmental Engineering, Inc., submitted written testimony on the estimated adverse environmental impacts that can occur if the New Animal Drug Application (NADA) for Baytril is withdrawn. Unfortunately, my testimony was ignored by the Administrative Law Judge in his Initial Decision ruling that the NADA for Baytril be withdrawn. My testimony and the important concerns raised therein should be reconsidered in this phase of the case.

It has been estimated that the withdrawal of the NADA for Baytril (i.e., allows the therapeutic use of this important therapeutic tool in broiler and turkey production) will significantly increase poultry mortality and condemnation of diseased birds at the processing plants, and the poultry industry will be required to increase the number of birds placed in the field and processed to offset these losses. The direct additional mortality and condemns resulting from the withdrawal of Baytril are estimated to result in significant adverse environmental impacts as well as corresponding detrimental impacts on human health and quality of life. Adverse impacts are anticipated for all environmental media (i.e., water, air and land) if Baytril is withdrawn. These adverse impacts were specifically identified in my testimony and/or testimony provided by others in this case.

Elimination of Baytril usage within the poultry industry may also cause significant indirect adverse impacts on the environment, human health and/or food safety. For example;

- Additional sick birds would likely be present on the "farm", and disease outbreaks would likely spread more rapidly to additional flocks and farms without this important therapeutic antibiotic;

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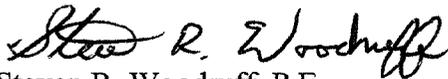
- The potential for the delivery of higher numbers of diseased birds to the processing plants will likely increase the level of pathogens on all birds processed into meat products; and
- Despite that other antibiotics are generally not as effective in controlling disease as Baytril, poultry producers (broilers and turkeys) will potentially increase the usage of these other antibiotics in an effort to control disease outbreaks, and these actions will result in the release of additional antibiotics into the environment.

These and other concerns need to be adequately considered in the agency's final decisions concerning the potential withdrawal of the NADA for Baytril. My testimony should also be adequately considered in the agency's evaluations on the continued therapeutic use of Baytril in broilers and turkeys.

Please contact me at (770) 844-0037 if you should have any additional questions concerning my testimony or the comments listed above.

Sincerely,

Woodruff & Howe Environmental Engineering, Inc.



Steven R. Woodruff, P.E.
President

cc: Docket 00N-1571