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MCDERMOTT, WILL & EMERY

May 18, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, Maryland 20852

Re: Enrofloxacin for Poultry: Withdraw of Approval of
New Animal Drug Application
NADA 140-828; FDA Docket 00N-1571
Bayer Corporation's Exceptions to Initial Decision

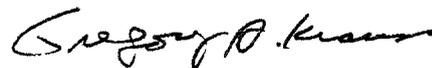
Dear Sir/Madam:

Enclosed please find a corrected Page 100 to Respondent Bayer Corporation's and Non-Party Participant Animal Health Institute's Exceptions to the Initial Decision that was filed with the Docket on May 17, 2004. This new page is being provided to the Docket to correct an internal citation error caused by a page numbering change after the Table of Contents was generated during finalization of the document.

The only change is to correct the internal citation. The referenced discussion of Dr. Burkhardt's analysis of the 67-person cohort is found at P.109-110 of Bayer's exceptions, rather than at P.115-116 as indicated in the originally-filed exceptions. The attached corrected page is identical to the one filed in all other respects.

I apologize for any inconvenience. Please do not hesitate to call if you have any questions.

Sincerely,



Gregory A. Krauss

GAK:jeh

Enclosure

cc: Nadine Steinberg, Esquire (w/enclosure)
Kent McClure, Esquire (w/enclosure)

WDC99 923131-1.048250.0013

2000N-1571

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6]. Clearly, according to this data set, this is not true for the majority of cases. However, even if these agents did shorten duration, Angulo's "proxy" conclusion is flawed since, as pointed out above, foreign travel is associated with a longer duration of illness, not shorter. Burkhart's evaluation of this 67-person cohort led him to the conclusion that, notwithstanding the purported statistically significant association between resistance and longer duration of diarrhea, the results were likely caused by chance. [See discussion of Burkhart's analysis of 67-person cohort, P.109-110, below].

The above facts seriously question Angulo's contention that travel is not a confounder, but a "proxy" for antidiarrheal mediation.

As discussed above, there are logical reasons to suspect that foreign-acquired infection might be a confounder, and a preponderance of the evidence clearly demonstrates that it is a confounder in CVM's studies seeking to evaluate whether there is a differential in duration of diarrhea between susceptible and resistant campylobacteriosis. Accordingly, the Initial Decision is not supported by evidence when it finds that foreign-acquired infections are not a confounder, and that the mechanism of resistance provides a basis to conclude "that there is no reason to believe fluoroquinolone-resistant *Campylobacter* infections acquired during foreign travel would be any different (i.e., result in a longer duration of diarrhea) than fluoroquinolone-resistant infections acquired domestically" and that "there is no reason to exclude foreign travel related cases when analyzing the association between the duration of diarrhea and fluoroquinolone susceptibility status of *Campylobacter* infections." [Initial Decision P.58].

(iv) Foreign-Acquired Infections Are Not Relevant To The Question Of Whether The Use Of Enrofloxacin In The U.S. Has An Adverse Impact On Human Health

An additional reason to remove foreign-acquired infections is that they are not related to the issue in this hearing, i.e., whether CVM has a reasonable basis to raise a serious question

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