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June 17, 2003

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

Re: Enrofloxacin for Poultry: Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828; FDA Docket: 00N-1571

Dear Mr. Jaffee:

This shall confirm our discussion today in which you informed me that Page 6 of the Proposed Order attached to *Bayer Corporation's Proposed Corrections in the Transcript of Oral Testimony* was missing from the copy submitted to the Dockets Management Branch on June 6, 2003. Enclosed is a copy of the missing page for the Docket.

My review of Bayer's filing and service copies leads me to conclude that the MS Word copy was complete, but that this page was also missing from the paper and .pdf copies provided to CVM, AHI and Judge Davidson. Nevertheless, I am confident that this clerical error did not affect Judge Davidson's decision. Judge Davidson's June 13, 2003 Order includes certain proposed corrections requested only by Bayer and embodied on the missing page (e.g., P.589 L.6; P.597 L.2; P.699 L.1; P.700 L.12, 13, 21 and 22).

I apologize for any inconvenience this clerical error may have caused. Please call with any questions.

Sincerely,



Gregory A. Krauss

GAK:jeh  
Enclosure

cc: Honorable Daniel J. Davidson  
Nadine Steinberg, Esquire  
Kent McClure, Esquire

WDC99 772594-1.048250.0013

2000N-1571

LET 15

579	1	chagella	Shigella
589	6	read	lead
589	18	here do you	here is do you
590	6	purposes today	purposes of today
597	2	final	find a
605	10	There is	There are
606	11	look	looked
609	5	CDD	CDC
616	7	time you think	time do you think

**WITNESS:** Marja-Liisa Hanninen

**DATE TAKEN:** May 5, 2003

Page	Line	As Transcribed	Change To
652	21-22	the enrofloxacin	their infection
663	4	indicate	indicated
666	1	norfloxacin	norfloxacin
666	2	ciprofloxacin	ciprofloxacin
666	5	ciprofloxacin	ciprofloxacin
670	1	inhuman	in human
670	16	cerafloxacin	sarafloxacin
672	9	statement	statements
673	8	flock	flocks
673	14	quite extensive	quite an extensive
675	11	so, if you think	so. I would think
675	12	those response.	dose/response.
675	14	those response.	dose/response.
676	4	there is difference	there is a difference
676	13	Your analysis	In your analysis
676	18	fluoroquinolone	fluoroquinolones
677	18	placed	based
678	1	end of '90s	end of the 90's
686	13	ciprofloxacin	ciprofloxacin
691	20	short on Sweden.	short follow-up on Sweden.
694	8	that	then
699	1	looking ahead	looking at that
699	5	seat	stipulations
700	12	spacial	spatial
700	13	Han Deneeling	Han deNeeling
700	21	Diana	Diane
703	2	Not	No
714	7	acid in chemotherapeutic agents isolated	acid resistance in Campylobacters isolated
718	13	not same	not the same