

**UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**In the Matter of:**

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

1918 03

**ORDER**

On June 6, 2003, pursuant to 21 C.F.R. § 12.98 (d) and the Order of May 9, 2003, Respondent Bayer and the Center for Veterinary Medicine (CVM) submitted proposed corrections to the transcript of the oral phase of this proceeding. On June 9, CVM submitted a request for clarification of the Order of May 9. CVM asks about the need for sworn declarations from witnesses in support of proposed corrections in their testimony.

Testimony reported in the official transcript is not subject to being changed or edited based on the recollections of counsel and/or witnesses. Misspoken words or omissions (if transcribed accurately) will not be corrected even if the witness honestly believes in the accuracy of the proposed correction. Since 21 C.F.R. § 12.98 (d) provides for the correction of transcription errors, only those proposed changes that correct **obvious** errors in transcription will be approved. While sworn declarations may aid in a finding of "transcription errors," such declarations are not determinative.

Accordingly, **IT IS ORDERED** that the following transcription error corrections be made in the official transcript of the hearing in this proceeding:

<b>Page</b>	<b>Line</b>	<b>As Transcribed</b>	<b>Change To</b>
2	N/A	Candace C. Ambrose	Candace K. Ambrose
4	19	Land	Lane
5	5	Candace C. Ambrose	Candace Ambrose
8	16	Patent	Patton
9	6	Patent	Patton
9	9	Ten-over	Tenover
11	2	Patent	Patton
11	4	12-A(5)	12.85
27	19	Cerofloxacin	Sarafloxacin
28	15	fluoroquinolones;	fluoroquinolones";
36	7	Greg,	Gregg,

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OR 46

52	10	TOPES	Tauxe's
55	4	of ruse	for use
55	6	Freedman	Friedman
56	19	CVM BOSE	CVM/Vose
57	1	CVM BOSE	CVM/Vose
58	22	ration	ratio
61	2	Dr. Freedman	Dr. Friedman
61	22	this come	this comes
62	5	"8 Chicken	Ate chicken
63	6	Freedman	Friedman
64	14	Freedman	Friedman
66	22	Freedman	Friedman
67	17	Freedman's	Friedman's
70	13	Homberg	Holmberg
70	14	Taket	Tacket
70	14	Conan Talkes	Cohen and Tauxe
70	14	Bivey	Bibi
71	1	Homberg	Holmberg
71	10	Taket	Tacket
71	20	Conan Talkes	Cohen and Tauxe
72	2	Bivey	Bibi
73	18	numbers	members
75	11	bed	be
79	9	around	are our
82	4	lori	lari
90	22	reviewed	reviewing
94	13	Minnick's	Minnich's
95	5	AR	ARS
97	3	D-	B-
100	1	understanding	understand
100	17-18	limit of protection	limits of detection
107	9	from2000	from 2000
108	8	laundry	monitoring
120	5	non-typoid	non-typhoid
120	8	typing	typhi
120	9	non-typing	non-typhi
120	13	non-typing	non-typhi
134	12	Which	Would
140	18	founded	rounded
153	13	no	not
154	8	Glysson	Glisson
154	19	Glysson's	Glisson's
154	21	Glysson's	Glisson's
155	8	Glysson's	Glisson's
155	12	Glysson's	Glisson's

157	4	Glysson	Glisson
157	12	ADUCA	AMDUCA
159	9	ADUCA	AMDUCA
161	13	did.	data.
162	21	ops	authors
165	15	Dr. Freedman	Dr. Friedman
166	14	Dr. Freedman	Dr. Friedman
168	1	Freedman	Friedman
170	22	Guilliam-Barre	Guillain-Barre
171	2	lead	Mead
171	11	lead	Mead
182	1	Guilliam-Barre	Guillain-Barre
182	4	Guilliam-Barre	Guillain-Barre
188	12	CVC	CDC
188	14	turnover	Tenover
189	11	CVC	CDC
192	1	Merkirk	Muirkirk
192	6-7	division of animal and food microbiology in the office of research	Division of Animal and Food Microbiology in the Office of Research
192	16	G-141	G-1481
193	9-10	rate points	breakpoints
193	10	two	to
200	18	interpreting	interpretative
203	1	free agents	reagents
204	1	micro-organisms	microorganisms
204	12	micro-organisms	microorganisms
205	14	micro-organism	microorganism
207	15	Amacolyte	macrolide
210	19	gastral enteritis	gastroenteritis
210	19	and	an
210	22	And is what's	And it is what's
217	9	am I offered it?	am I off of it?
217	12	Am I offered it?	Am I off of it?
222	9	CVC	CDC
222	10	CVC	CDC
225	17	then	when
236	5	enterobacteriosis,	Enterobacteriaceae
238	13	gastro-enteritis	gastroenteritis
238	18	pharmaco-kinetic	pharmaco-kinetics
243	20	whether that antimicrobial is	whether that an antimicrobial is
248	7	discrimination	distribution
251	6	applicacy	efficacy
251	10	enterobacteracin	enterobacteriaceae
251	17	and an enteritis	an enteritis

252	9	of	or
254	13	Gentamiacin	Gentamicin
259	10	fine little	bimodal
267	10	attachment.	attachments.
268	16	jejune	jejuni
269	22	offer	author
271	22	till	until
272	2	till	until
276	6	microbiology	biology
279	11	date versus	data versus
279	11	date which	data which
285	1	apriority	<i>a priori</i>
293	16	grahms	gram
294	2	Chicatoxin	shiga toxin
294	5	Chagilla	Shigella
294	17	Chagilla	Shigella
296	16	Campyl	Campylobacter
303	4	emerging infections program	Emerging Infections Program
303	5-6	emerging infections program	Emerging Infections Program
306	4	Hard Net	Hardnett
306	16	site	cite
309	1	HardNet	Hardnett
310	3	Hard Net	Hardnett
322	4	food safety inspection service	Food Safety Inspection Service
322	7	call	all
322	8	venting	vetting
338	1	or E. coli	or coli
344	19	grahms	grams
345	12	juni	jejuni
345	17	to juni	jejuni
346	4	isolate	isolates
346	6	it's	its
349	1	resistant	resistance
349	12	MCI	MIC
351	21	or	for
353	11	had an effective	had ineffective
360	3	aggression	regression
370	14	contaminates	contaminants
374	22	juni	jejuni
395	13	1, 028	1,028
395	15	was89	was 89
399	9	as	is
404	10	controlled	control
414	20	Alteri	poultry
420	5	pipperate	hippurate

427	13	is the transcript	as the transcript
427	18-19	merely an audible	nearly inaudible
431	20	MR. NICHOLAS	MR. SPILLER
433	1	899	A-99
448	17	medium	median
449	22	resistance	resistant
457	13	Karl Mollbach	Kare Molbak
457	15	Mollbach	Molbak
460	19	apriority	<i>a priori</i>
461	2	apriority	<i>a priori</i>
462	10	apriority	<i>a priori</i>
462	12	apriority	<i>a priori</i>
463	5	apriority	<i>a priori</i>
463	8	multi-variant	multivariate
465	12	multi-variant	multivariate
465	13-14	multi-variant	multivariate
465	15	aggression	regression
465	16	variants	variance
466	3	multi-varied	multivariate
467	2	multi-varied	multivariate
467	7-8	multi-variant	multivariate
467	10	apriority	<i>a priori</i>
475	5	Ms. Zuckerman	Judge Davidson
475	9	Ms. Zuckerman	Judge Davidson
484	3	norms	NARMS
484	7	scan.	scheme.
487	17	Greenbriar Drive, Lionel	Green Briar Drive, Lino
492	12	review	reviewer
494	6	former	formal
494	18	methods analytical	methods and analytical
497	4	Embry,	Emery,
503	2	Pyddic, Gunn,	Piddock, Gaunt,
503	3	Thruolphal,	Threlfall,
503	4	Thruolphal	Threlfall
504	5	Pro crit	purpose
507	8	separate	hippurate
508	1	genes.	genus.
508	2	genes?	genus?
516	19	TCR	PCR
521	5	flore-typing	fla typing
521	14	great.	correct.
523	11	to	as
532	5	flagellum	flagellin
536	2	flaw	fla
536	5	flaw-typing	fla typing

536	8	Nachompkin	Nachamkin
536	11	Nachompkin	Nachamkin
536	15	flaw	fla
536	20	Flaw	Fla
536	20	F-L-A-W.	F-L-A.
536	21	Flaw	Fla
547	9	flawed	fla
554	19	Ms. Zuckerman	Judge Davidson
555	3	FOR	FOI
555	7	FOR	FOI
555	20	FOR	FOI
556	6	FLAG	FLA
556	20	to doing	jejuni
557	13	and	in
567	17	packaging	pathogens
572	2	CBM's	CVM's
578	13	infectious diseases	Infectious Diseases
579	1	chagella	Shigella
587	15	salmonella	Salmonella
589	1	campylobacter	Campylobacter
589	6	read	lead
597	2	final	find a
609	5	CDD	CDC
615	20	uni-variant	univariate
618	1	uni-variant	univariate
618	3	uni-variant	univariate
618	6	multi-variant	multivariate
620	22	multi-variant	multivariate
628	17	CBM	CVM
634	N/A	Candace C. Ambrose	Candace K. Ambrose
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
675	12	those	dose
675	14	those	dose
676	18	fluoroquinolone	fluoroquinolones
677	18	placed	based
686	6	fetal	fecal
686	13	ciprofloxacin	ciprofloxacin
692	14	Denmark	DANMAP
695	6	015	0.5

699	1	looking ahead	looking at that
700	12	spacial	spatial
700	13	Han Deneeling	Han deNeeling
700	21	Diana	Diane
703	22	Pemont	Plymouth
703	22	Tweitz	Thwaites
718	9	10 to 15	10 to 50
725	N/A	Candace C. Ambrose	Candace K. Ambrose
730	7	firm in Washington address	firm's Washington address
738	16	sales were pointing	cells were pointing
738	19	stateholders	stakeholders
740	9	campylobacterial	campylobacter
742	18	in m questions	in my questions
746	3	attachment	catchment
747	1	welcomed	welcome
747	6	the ideal	the "ideal
747	7	incident	incidence
748	5	detachment	the catchment
751	15	determinate	determinant
751	18	through various sorts	through various sources
753	7	"multi - varied	"multivariate
753	10	population, attributable	population attributable
754	6	population, attributable	population attributable
754	9	There's "A," undercooked or pink chicken.	There's "Ate undercooked or pink chicken."
754	10	"A" chicken prepared at home	"Ate chicken prepared at home"
754	14	"A," undercooked or pink chicken,	"Ate undercooked or pink chicken",
756	12	question	questions
763	11-12	on the evidence cause.	in evidence law.
763	18	Registrar	Register
768	16	limitation is	limitation of
768	17	risks	risk
770	3	ACRIORI	<i>a priori</i>
770	13	A	Q
772	16	reduction	fraction
774	4-6	the "A" chicken prepared in the restaurant has 44	the "Ate chicken prepared at a restaurant" has 24
774	9	says, " 'A' chicken	says, "Ate chicken
775	5	respond, yes	respond, "yes
775	6	home would	home "would
775	8	said yes	said "yes
775	9	home than	home" than
779	4	attachment 29	attachment 1
782	22	Schmidt	Schmid

787	10	I said, more	I said, "more
787	11	undercooked.	undercooked."
788	18	Schmitz study in Debuque	Schmid study in Dubuque
789	4	Debuque	Dubuque
790	16	as the question.	ask the question.
790	19	Rodriguez	Rodrigues
791	5	Rodriguez	Rodrigues
791	17	Rodriguez	Rodrigues
792	18	Schmitz	Schmid
792	20	Rodriguez	Rodrigues
794	22	contamination	contaminated
797	4	CVC	CDC
800	8	At if	And if
802	8	slip of	flip of
802	18	indication	etiologic
803	9	CVC	CDC
803	16	injecting	ingesting
803	21	CVC	CDC
804	13	Floraquinolone	fluoroquinolone
805	18	Predence	Friedman
805	19	Predence	Friedman
805	20	CVC	CDC
806	8-9	Drank untreated water from a lake, river, or stream.	"Drank untreated water from a lake, river, or stream."
806	19	Floraquinolone	fluoroquinolone
809	11	Norm's	NARM's
810	14	proposition trivial	population attributable
812	2	know	known
812	6	resistant	resistance
821	13	Ciprofloxacin	ciprofloxacin
822	2	it says number of	it says "number of
822	4	Ciprofloxacin -- 27; and it says	ciprofloxacin -- 37"; and it says
822	9	had -- one of the patients	had -- among patients
822	21	"Of the	"Among
823	4	Ciprofloxacin	ciprofloxacin
825	10	Aithromycin	azithromycin
825	11	Ciprofloxacin	ciprofloxacin
825	20	"Recovery	"Recovered
826	1	Azithromycin	azithromycin
826	2	Azithromycin	azithromycin
826	3	Ciprofloxacin	ciprofloxacin
830	18	Exhibit 9433.	Exhibit G-953.
830	21	Table 1.2?	Table I.2?
831	4	I think it's 1.2,	I think it's I.2,
831	10	31 in 34,945	1 in 34,945



832	20	MR. SPILLER:	MR. NICHOLAS:
726	4	Louie Cox, Jr.	Louis Cox, Jr.
834	22	Louie Anthony Cox, Jr.	Louis Anthony Cox, Jr.
841	10	her	him
843	2	MR. SPILLER:	MR. NICHOLAS:
843	22	Ms. Stenberg	Ms. Steinberg
849	22	checking	chicken
850	15	associations.	associations?
853	10	core six.	course six.
854	9	none exist.	none exists.
856	18	I rush to say	I blush to say
867	9	thought keys	thought piece
869	3-5	yet the probability that exactly one person will become ill may be less than the probably that two or more will become ill, right?	“yet the probability that exactly one person will become ill may be less than the probably that two or more will become ill, right?”
869	14-15	I did say this seems to me to be a very practical, sound approach. I have no remaining concern.	I did say, “This seems to me to be a very practical, sound approach. I have no remaining concerns.”
870 - 871	22 - 1	if several people in the same family get sick, it's an outbreak.	if several people in the same family get sick, is it an outbreak?
878	18-19	where you try to say is this model correct and useful.	where you try to say, “Is this model correct and useful?”
878	20-21	saying do its consequences follow from its premises,	Saying, “Do its consequences follow from its premises?”,
878	22	empirically valid.	empirically valid?
880	13	carried out? Question.	carried out?
880	19	Virginia Misen	Virginiamycin
883	20-21	the number of contracts.	a number of contracts.
890	14	progression models	regression models
892	1-3	This is a reference for the rather-than-chicken assumption, per se, portion, not for the restaurant dining portion.	This is a reference for the “rather-than-chicken consumption, per se” portion, not for the “restaurant dining” portion.
894	2	the T value	the p value
895	1	I love that data step.	I love that data set.
895	9	Dr. Angelo’s	Dr. Angulo’s
895	11	Dr. Angelo’s	Dr. Angulo’s
898	15	restaurant dining, but the not chicken per se point.	“restaurant dining”, but the “not chicken per se” point.
898	17-18	My point is, why.	My point is, Why?

904	15-16	I think there is probably a host of these interactions.	I think there is probably a host-disease interaction.
906	13	logistic progression	logistic regression
908	15	math odds ratio	matched odds ratio
912	19	No, it's seem to support.	No, it's "seem to support".
919	15	resubmitted in	resubmit it in a
925	3	Louie Cox, Jr.	Louis Cox, Jr.
925	6	LOUIE COX, JR.	LOUIS COX, JR.
930	9	Michael Bond	Michael Vaughn
931	1	Dr. DeGrowth.	Dr. DeGroot.
931	19	Dr. DeGrowth	Dr. DeGroot
932	14	Dr. DeGrowth	Dr. DeGroot
937	5, 10	Rodriguez	Rodrigues
938	1	Eberhart Phillips	Eberhart-Phillips
941	20	Louie Cox, Jr.	Louis Cox, Jr.
946	1	reduction stage.	production stage.
947	3	has provided that	has requested that
947	13	the lines begins with	the line begins with
949	2	it says the minor.	it says: "The minor...".
951	19	relatively large.	"relatively large".
955	5	For example, a reduction of three log 10 colony forming units per chicken.	"For example, a reduction of three log 10 colony forming units per chicken."
955	18	We struck out even after	We struck out "even after
955	19	log units	log units"?
970	11	as a form for	as a farm-to-fork
970	17	flat prevalence	flock prevalence
970	19	flat prevalence	flock prevalence
971	4	microbial lode	microbial load
971	10	Prevalence says not how many microbes is this chicken carrying; prevalence says what fraction of flocks in this case have at least some campylobacter present.	Prevalence says not, "How many microbes is this chicken carrying?" Prevalence says, "What fraction of flocks in this case have at least some campylobacter present?"
972	16	microbial load has held constant	microbial load is held constant
981	2	Rodriguez	Rodrigues
982	16, 16, 21	Rodriguez	Rodrigues
983	3, 4, 19	Rodriguez	Rodrigues
984	3	direction	objection
984	13, 14, 20	Rodriguez	Rodrigues
985	1	Rodriguez	Rodrigues
986	6, 7, 8, 17	Rodriguez	Rodrigues
987	18	Rodriguez	Rodrigues

998	17	chickenless	chicken, less
999	4	which I interpreted.	“which I interpreted”.
999	17	NOO page.	NOOH.
1001	14	lamda.	lambda
1012	2	dose-responsive model	dose-response model
1024	3	your model,	“your model”,
1028	11	sensitivity analysis provides partial solution to the problem of unknown variable dose response relations.	“Sensitivity analysis provides a partial solution to the problem of unknown and variable dose response relations.”
1033	19	you’re a-17?	your A-17?
1034	3, 15, 22	Tunis	Teunis
1035	14, 22	Tunis	Teunis
1037	1	Tunis	Teunis
1039	11, 14	Tunis	Teunis
1040	17	Tunis	Teunis
1041	19	he did that here.	he did that here?
1042	13, 16	Tunis	Teunis
1042	18	I could find myself	I confined myself
1043	14, 18	Tunis	Teunis
1044	7	Tunis	Teunis
1045	12	partner	partner’s
1045	13	Popkin	Popken
1046	1	Tunis	Teunis
1048	10-11	dose response at data plot.	dose-response data plot?
1048	12	Tunis	Teunis
1053	21	a bilinear probability	a binomial probability
1054	2	bilinear distribution,	binomial distribution,
1056	22	In this role of the table, yes.	In this row of the table, yes.
1059	1-2	rinse aid	rinsate
1063	22	medium	median
1066	10	certain,	Cauchy
1069	9	chicken concerned	chicken consumed
1069	18	fit a layer of direction	fit a linear regression
1071	5	You picked the regression equation for this.	Who picked the regression equation for this?
1076	11	aggression	regression
1077	8	the readers or your testimony	the readers of your testimony
1085	11	FDA.	USDA.
1092	15	predictable	predicting
1095	12	Rodriguez	Rodrigues
1098	14	Rodriguez	Rodrigues

1103	10	controlled	control
1105	12	Erisycolitis	air sacculitis
1105	12	Erisycolitis	air sacculitis
1106	4	Erisycolitis	air sacculitis
1108	3, 21	Rodriguez	Rodrigues
1108	5	are saying it doesn't	are saying: "it doesn't
1108	6	it be	it be?
1108	7	drug.	drug?"
1113	2	your	you're
1114	20	called eight chick.	called "ate" chick.
1114	21	Eight chick,	"Ate chick",
1116	17	vis farm,	"vis farm",

DATED this 13<sup>th</sup> day of June, 2003.

/s/ Daniel J. Davidson  
Daniel J. Davidson  
Administrative Law Judge