

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

JUN 11 2003 11:56 AM

)
)
)
In the Matter of:)


FDA DOCKET: 00N-1571
DATE: June 6, 2003

Enrofloxacin for Poultry: Withdrawal)
of Approval of Bayer Corporation's)
New Animal Drug Application)
(NADA) 140-828 (Baytril))
)
)
)
)
_____)

Center for Veterinary Medicine's Proposed Corrections in the Enrofloxacin Hearing Transcript

Pursuant to the Administrative Law Judge's Order dated May 9, 2003, the Center for Veterinary Medicine respectfully submits the attached proposed corrections in the Enrofloxacin Hearing Transcript. These proposed corrections are submitted in the form of individual declarations from the Center's counsel and witnesses in this hearing.

Respectfully submitted:


Nadine Steinberg
Counsel for the Center for Veterinary Medicine

2000N-1571

LET 12

Enrofloxacin Hearing
Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Proposed Corrections to the Transcript was hand delivered this 6th day of June, 2003, to:

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

I also certify that a copy of the Center for Veterinary Medicine's Proposed Corrections has been hand delivered and e-mailed, this 6th day of June, 2003, to:

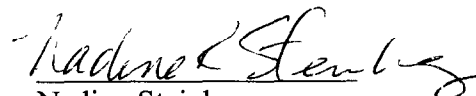
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy of the Center for Veterinary Medicine's Proposed Corrections was e-mailed and mailed by First Class U.S. mail, this 6th day of June, 2003, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

Dated: 6/6/03


Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050

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

| | | |
|--------------------------------------|---|----------------------|
| |) | |
| |) | |
| |) | |
| In the Matter of: |) | FDA DOCKET: 00N-1571 |
| |) | DATE: June 6, 2003 |
| Enrofloxacin for Poultry: Withdrawal |) | |
| of Approval of Bayer Corporation's |) | |
| New Animal Drug Application |) | |
| (NADA) 140-828 (Baytril) |) | |
| |) | |
| |) | |
| |) | |
| |) | |

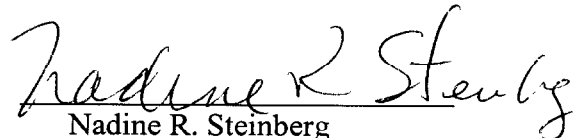
Declaration of Nadine R. Steinberg

I, Nadine R. Steinberg, counsel for FDA's Center for Veterinary Medicine, make this declaration based upon my review of the hearing transcripts, dated April 28, 2003 through May 7, 2003, in the above-entitled matter. I note the following corrections to the transcription of my statements:

| <u>Date</u> | <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|-------------|-------------------|-------------------------|
| 4/28/2003 | 4 | 19 | Land | Lane |
| 4/28/2003 | 153 | 13 | no | not |
| 4/28/2003 | 154 | 19 | Glysson's | Glisson's |
| 4/28/2003 | 154 | 21 | Glysson's | Glisson's |
| 4/28/2003 | 171 | 2 | lead | Mead |
| 4/28/2003 | 171 | 11 | lead | Mead |
| 4/29/2003 | 248 | 7 | discrimination | distribution |

| <u>Date</u> | <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|-------------|-------------------|-------------------------|
| 4/29/2003 | 251 | 6 | applicacy | efficacy |
| 4/29/2003 | 252 | 9 | of | or |
| 4/29/2003 | 253 | 2 | solutions | species |
| 4/29/2003 | 259 | 10 | fine little | bimodal |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.


Nadine R. Steinberg
Counsel for CVM

6/4/03
Date

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

| | | |
|--------------------------------------|---|----------------------|
| |) | |
| |) | |
| |) | |
| In the Matter of: |) | FDA DOCKET: 00N-1571 |
| |) | DATE: June 6, 2003 |
| Enrofloxacin for Poultry: Withdrawal |) | |
| of Approval of Bayer Corporation's |) | |
| New Animal Drug Application |) | |
| (NADA) 140-828 (Baytril) |) | |
| |) | |
| |) | |
| |) | |
| |) | |

Declaration of Robert M. Spiller, Jr.

I, Robert M. Spiller, Jr., one of CVM's counsel in this matter, make this declaration based upon my review of the transcript of my statements and questions in the oral cross examination hearing, for this matter. I note the following corrections to the transcription of my statements and questions:

| <u>Page</u> | <u>Line</u> | <u>Transcript Reads:</u> _____ | <u>Transcript Should Read:</u> |
|-------------|-------------|--------------------------------|--------------------------------|
| 427 | 13 | is the transcript | as the transcript |
| 427 | 18-19 | merely an audible | nearly inaudible |
| 428 | 13 | transcribed, have | transcribed, they have |
| 832 | 20 | MR. SPILLER: | MR. NICHOLAS: |
| 843 | 2 | MR. SPILLER: | MR. NICHOLAS: |
| 843 | 22 | Ms. Stenberg | Ms. Steinberg |
| 880 | 13 | carried out? Question. | carried out? |

| | | | |
|------|-------|--------------------------|------------------------------|
| 894 | 2 | the T value | the p value |
| 938 | 1 | Eberhart Phillips | Eberhart-Phillips |
| 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 | 9 | Do you have a relatively | Do you have: "a relatively |
| 951 | 10 | for example -- | for example" -- |
| 951 | 19 | relatively large. | "relatively large". |
| 955 | 18 | We struck out even after | We struck out "even after |
| 955 | 19 | log units | log units"? |
| 970 | 17 | flat prevalence | flock prevalence |
| 970 | 19 | flat prevalence | flock prevalence |
| 984 | 3 | direction | objection |
| 988 | 18 | in quoting 9 percent | in, quoting: "49 percent" |
| 997 | 18 | that FDA is based on | that FDA's model is based on |
| 998 | 13-14 | very near bottom 4(c) | very near the bottom: 4.4(c) |
| 998 | 17 | chickenless | chicken, less |
| 1012 | 2 | dose-responsive model | dose-response model |
| 1015 | 6 | posted on the Internet | posted it on the Internet |
| 1030 | 4-5 | you don't have any | you don't know how many |
| 1033 | 19 | you're a-17? | your A-17 ? |
| 1035 | 12-13 | In other study | In any other study |
| 1041 | 10 | about plots. | about data plots? |

| | | | |
|------|-------|-------------------------------|-------------------------------|
| 1041 | 19 | he did that here. | he did that here? |
| 1045 | 12 | partner | partner's |
| 1048 | 10-11 | dose response at data plot. | dose-response data plot? |
| 1059 | 1-2 | rinse aid | rinsate |
| 1069 | 9 | chicken concerned | chicken consumed |
| 1069 | 18 | fit a layer of direction | fit a linear regression |
| 1076 | 11 | linear aggression | linear regression |
| 1077 | 8 | the readers or your testimony | the readers of your testimony |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Robert M. Spiller, Jr.
 Robert M. Spiller, Jr.

5 JUN 03
 Date

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

| | | |
|--------------------------------------|---|----------------------|
| |) | |
| |) | |
| |) | |
| In the Matter of: |) | FDA DOCKET: 00N-1571 |
| |) | DATE: June 6, 2003 |
| Enrofloxacin for Poultry: Withdrawal |) | |
| of Approval of Bayer Corporation's |) | |
| New Animal Drug Application |) | |
| (NADA) 140-828 (Baytril) |) | |
| |) | |
| |) | |
| |) | |
| |) | |

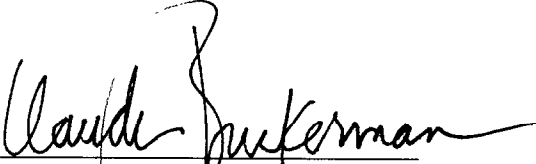
Declaration of Claudia J. Zuckerman

I, Claudia J. Zuckerman, counsel for FDA's Center for Veterinary Medicine, make this declaration based upon my review of the hearing transcripts, dated April 28, 2003; April 30, 2003; May 1, 2003; May 2, 2003; and May 6, 2003, in the above-entitled matter. I note the following corrections to the transcription of my statements:

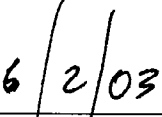
| <u>Date</u> | <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|-------------|-------------------|---------------------------|
| 4/28/2003 | 8 | 16 | Patent | Patton |
| 4/28/2003 | 9 | 6 | Patent | Patton |
| 4/28/2003 | 9 | 9 | Ten-over | Tenover |
| 4/28/2003 | 11 | 2 | Patent | Patton |
| 4/28/2003 | 11 | 4 | 12-A(5) | 12.85 |
| 4/30/2003 | 467 | 22 | Fluoroquinolone | Fluoroquinolone-resistant |
| 4/30/2003 | 475 | 5 | Ms. Zuckerman | Judge Davidson |

| | | | | |
|-----------|-----|----|----------------|------------------|
| 4/30/2003 | 475 | 9 | Ms. Zuckerman | Judge Davidson |
| 5/01/2003 | 554 | 19 | Ms. Zuckerman | Judge Davidson |
| 5/01/2003 | 555 | 3 | FOR | FOI |
| 5/01/2003 | 555 | 7 | FOR | FOI |
| 5/01/2003 | 555 | 20 | FOR | FOI |
| 5/01/2003 | 556 | 6 | FLAG | FLA gene |
| 5/01/2003 | 557 | 13 | and | in |
| 5/02/2003 | 618 | 3 | uni-variant | univariate |
| 5/02/2003 | 618 | 6 | multi-variant | multivariate |
| 5/02/2003 | 620 | 22 | multi-variant | multivariate |
| 5/02/2003 | 628 | 17 | CBM | CVM |
| 5/06/2003 | 919 | 15 | resubmitted in | resubmit it in a |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.



 Claudia J. Zuckerman
 Counsel for CVM



 Date

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

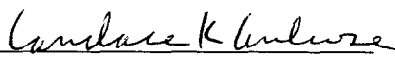
| | |
|--|--|
|))) In the Matter of:)) Enrofloxacin for Poultry: Withdrawal) of Approval of Bayer Corporation's) New Animal Drug Application) (NADA) 140-828 (Baytril)))))) | FDA DOCKET: 00N-1571 DATE: June 6, 2003 |
|--|--|

Declaration of Candace K. Ambrose

I, Candace K. Ambrose, counsel for FDA's Center for Veterinary Medicine, make this declaration based upon my review of the hearing transcripts, dated April 28, 2003; May 5, 2003; and May 6, 2003, in the above-entitled matter. I note the following corrections to the transcription of my name:

| <u>Date</u> | <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|-------------|--------------------|-------------------------|
| 4/28/03 | 2 | N/A | Candace C. Ambrose | Candace K. Ambrose |
| 4/28/03 | 5 | 5 | Candace C. Ambrose | Candace Ambrose |
| 5/5/03 | 634 | N/A | Candace C. Ambrose | Candace K. Ambrose |
| 5/6/03 | 725 | N/A | Candace C. Ambrose | Candace K. Ambrose |

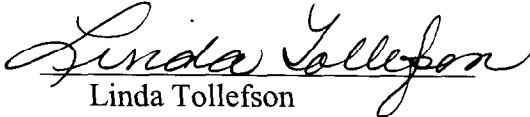
I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.


 Candace K. Ambrose
 Counsel for CVM

6-5-03
 Date

| Date | Page | Line | Text Reads | Text Should Read |
|-------------|-------------|-------------|--|---|
| 4/28/2003 | 73 | 18 | numbers in | members of |
| 4/28/2003 | 79 | 9 | around | are our |
| 4/28/2003 | 90 | 22 | reviewed | reviewing |
| 4/28/2003 | 94 | 13 | Minnick's | Minnich's |
| 4/28/2003 | 95 | 5 | AR | ARS |
| 4/28/2003 | 100 | 17-18 | limit of protection | limits of detection |
| 4/28/2003 | 108 | 8 | laundry | monitoring |
| 4/28/2003 | 120 | 8 | typing | Typhi |
| 4/28/2003 | 121 | 14-15 | They not all be susceptibility testing. | They would not all be susceptibility tested. |
| 4/28/2003 | 157 | 12 | ADUCA | AMDUCA |
| 4/28/2003 | 161 | 13 | did. | data. |
| 4/28/2003 | 162 | 20-21 | co-ops. | co-authors. |
| 4/28/2003 | 170 | 22 | Guilliam-Barre | Guillian-Barré |
| 4/28/2003 | 174 | 2 | It | The |
| 4/28/2003 | 176 | 2 | then proportion | the proportion |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.


Linda Tollefson
CVM

6-4-03
Date

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

| | | |
|--------------------------------------|---|----------------------|
| |) | |
| |) | |
| |) | |
| In the Matter of: |) | FDA DOCKET: 00N-1571 |
| |) | DATE: June 6, 2003 |
| Enrofloxacin for Poultry: Withdrawal |) | |
| of Approval of Bayer Corporation's |) | |
| New Animal Drug Application |) | |
| (NADA) 140-828 (Baytril) |) | |
| |) | |
| |) | |
| |) | |

Declaration of Robert D. Walker

I, Robert D. Walker, make this declaration based upon my review of the hearing transcript, dated April 29, 2003, in the above-entitled matter. I note the following corrections to the transcription of my statements:

| <u>Date</u> | <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|-------------|--|--|
| 4/29/2003 | 192 | 1 | Merkirk | Muirkirk |
| 4/29/2003 | 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 |
| 4/29/2003 | 192 | 16 | G-141 | G-1481 |
| 4/29/2003 | 193 | 9-10 | rate points | breakpoints |
| 4/29/2003 | 193 | 10 | two | to |
| 4/29/2003 | 200 | 18 | interpreting | interpretative |
| 4/29/2003 | 206 | 16 | suspension incubator | suspension, incubate it |

| <u>Date</u> | <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|-------------|-----------------------------------|---|
| 4/29/2003 | 208 | 18-19 | organ susceptible for an organism | a microorganism susceptible to that antimicrobial agent |
| 4/29/2003 | 216 | 22 | humans | animals |
| 4/29/2003 | 217 | 9 | offered | off of |
| 4/29/2003 | 217 | 12 | offered | off of |
| 4/29/2003 | 222 | 9 | CVC | CDC |
| 4/29/2003 | 225 | 17 | then | when |
| 4/29/2003 | 237 | 6 | type organisms to that drug | organisms to be treated by that drug |
| 4/29/2003 | 251 | 10 | enterobacteracin | enterobacteriaceae |
| 4/29/2003 | 251 | 17 | and an enteritis | an enteritis |
| 4/29/2003 | 254 | 13 | Gentamiacin | Gentamicin |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

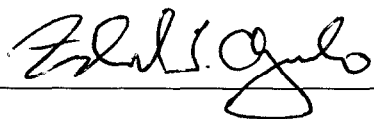
Robert D Walker
 Robert D. Walker
 CVM

6.4.03
 Date

| | | | |
|-----|-------|--------------------------------|--------------------------------|
| 294 | 17 | Chagilla | Shigella |
| 296 | 16 | Campyl | Campylobacter |
| 297 | 5 | Our there are staff | Our -- there are staff |
| 303 | 4 | emerging infections program | Emerging Infections Program |
| 303 | 5-6 | emerging infections program | Emerging Infections Program |
| 322 | 4 | food safety inspection service | Food Safety Inspection Service |
| 322 | 7 | They call come in | They call, come in |
| 322 | 8 | venting | vetting |
| 344 | 19 | grahms | grams |
| 345 | 12 | juni | jejuni |
| 345 | 14-15 | non-E. coli | non-coli |
| 345 | 17 | to juni | jejuni |
| 346 | 6 | it's | its |
| 349 | 12 | MCI | MIC |
| 360 | 3 | aggression | regression |
| 364 | 14 | presence | prevalence |
| 370 | 14 | contaminates | contaminants |
| 414 | 20 | Alteri | poultry |
| 420 | 5 | pipperate | hippurate |
| 457 | 13 | Karl Mollbach | Kare Molbak |
| 457 | 15 | Mollbach | Molbak |
| 460 | 19 | apriority | a priori |
| 461 | 2 | apriority | a priori |

| | | | |
|-----|-------|---------------|--------------|
| 462 | 10 | apriority | a priori |
| 462 | 12 | apriority | a priori |
| 463 | 5 | apriority | a priori |
| 463 | 8 | multi-variant | multivariate |
| 465 | 12 | multi-variant | multivariate |
| 465 | 13-14 | multi-variant | multivariate |
| 465 | 15 | aggression | regression |
| 465 | 16 | variants | variance |
| 465 | 17 | variants | variables |
| 466 | 3 | multi-varied | multivariate |
| 467 | 2 | multi-varied | multivariate |
| 467 | 7-8 | multi-variant | multivariate |
| 467 | 10 | apriority | a priori |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.



Frederick J. Angulo

6-4-03

Date

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

| | | |
|--------------------------------------|---|----------------------|
| |) | |
| |) | |
| |) | |
| In the Matter of: |) | FDA DOCKET: 00N-1571 |
| |) | DATE: June 6, 2003 |
| Enrofloxacin for Poultry: Withdrawal |) | |
| of Approval of Bayer Corporation's |) | |
| New Animal Drug Application |) | |
| (NADA) 140-828 (Baytril) |) | |
| |) | |
| |) | |
| |) | |
| |) | |

Declaration of Kirk E. Smith

I, Kirk E. Smith, make this declaration based upon my review of the hearing transcript, dated May 1, 2003, in the above-entitled matter. I note the following corrections to the transcription of my testimony:

| <u>Page</u> | <u>Line</u> | <u>Text Reads</u> | <u>Text Should Read</u> |
|-------------|-------------|--------------------------|-------------------------|
| 487 | 17 | Greenbriar Drive, Lionel | Green Briar Drive, Lino |
| 503 | 2 | Pyddic, Gunn | Piddock, Gaunt |
| 503 | 3 | Thruolphal | Threlfall |
| 507 | 8 | separate | hippurate |
| 508 | 1 | genes | genus |
| 532 | 5 | flagellum | flagellin |
| 536 | 8 | Nachompkin | Nachamkin |
| 547 | 7 | die of | define |

| | | | |
|-----|----|---------------|-------------|
| 547 | 9 | flawed | fla |
| 547 | 19 | inappropriate | appropriate |
| 551 | 9 | do not do | did not do |
| 556 | 20 | to doing | jejuni |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Kirk Smith

Kirk E. Smith

6-2-03

Date

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

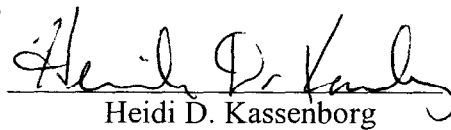
| | |
|---|--|
|)) In the Matter of:)) Enrofloxacin for Poultry: Withdrawal) of Approval of Bayer Corporation's) New Animal Drug Application) (NADA) 140-828 (Baytril)))) | FDA DOCKET: 00N-1571 DATE: June 6, 2003 |
|---|--|

Declaration of Heidi D. Kassenborg

I, Heidi D. Kassenborg, make this declaration based upon my review of the hearing transcript, dated May 2, 2003, in the above-entitled matter. I note the following corrections to the transcription of my testimony:

| Page | Line | Text Reads | Text Should Read |
|------|------|------------------------------|------------------------------|
| 578 | 13 | Clinical infectious diseases | Clinical Infectious Diseases |
| 579 | 1 | chagella | Shigella |
| 587 | 15 | salmonella | Salmonella |
| 589 | 1 | campylobacter | Campylobacter |
| 615 | 20 | uni-variant | univariate |
| 618 | 1 | uni-variant | univariate |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.


 Heidi D. Kassenborg

6/2/2003
 Date

| | | | |
|-----|----|--------------------|------------------------|
| 672 | 22 | the medical | the veterinary medical |
| 675 | 12 | those | dose |
| 675 | 14 | those | dose |
| 677 | 18 | placed | based |
| 680 | 11 | believe natural | believe on natural |
| 686 | 6 | fetal | fecal |
| 688 | 21 | where | which |
| 688 | 22 | in -- | acquired |
| 688 | 22 | from | but |
| 689 | 21 | Rautelin -- | Rautelin and Hänninen |
| 692 | 14 | Denmark | DANMAP |
| 695 | 6 | 015 | 0.5 |
| 695 | 22 | in -- | in human medicine |
| 697 | 12 | pages | dates |
| 701 | 21 | building | participating within |
| 703 | 22 | Pemont | Plymouth |
| 703 | 22 | Twertz | Thwaites |
| 709 | 11 | here -- own expert | here your own experts |
| 710 | 10 | my -- | my testimony |
| 714 | 1 | not -- | not told |
| 716 | 4 | monitored | monitoring |
| 718 | 9 | 10 to 15 | 10 to 50 |
| 718 | 11 | level -- | level of |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.



Marja-Liisa Hänninen, Ph.D.

03/06 2003

Date

| | | | |
|-----|-------|--|---|
| 753 | 7-9 | multi-varied analysis and derived population, attributable fractions, Campylobacteriosis, case control study, 1998, 1999 | multivariate analysis and derived population attributable fractions, Campylobacter case control study, 1998, 1999 |
| 754 | 9 | No. There's "A," undercooked or pink chicken. | No. There's ate undercooked or pink chicken. |
| 755 | 21-22 | FoodNet in the case | FoodNet case |
| 770 | 3 | had established ACRIORI | had established <i>a priori</i> |
| 770 | 13 | A | Q |
| 803 | 15-16 | consumptions -- the way we use consumption is not individuals sitting around injecting chicken. | consumption -- the way we use consumption is not individuals sitting around ingesting chicken. |
| 803 | 21 | the CVC data | the CDC data |
| 804 | 13 | Floraquinolone | fluoroquinolone |
| 809 | 11 | Norm's data | NARMS data |
| 812 | 2 | not know | not known |
| 821 | 16 | have not read it from | have not read it for |
| 831 | 10 | mean in 1998 was 31 in 34,945 | mean in 1998 was 1 in 34,945 |

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Mary J. Bartholomew
Mary J. Bartholomew

6/3/03
Date