

A Partnership Including
Professional Corporations
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
202-756-8000
Facsimile 202-756-8087
www.mwe.com

Robert B. Nicholas
Attorney at Law
rnicholas@mwe.com
202-756-8170

Boston
Chicago
London
Los Angeles
Miami
Moscow
New York
Orange County
Silicon Valley
Vilnius
Washington, D.C.

MCDERMOTT, WILL & EMERY

April 22, 2002

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

**IN THE MATTER OF NOTICE OF HEARING:
PROPOSAL TO WITHDRAW APPROVAL OF NEW
ANIMAL DRUG APPLICATION FOR ENROFLOXACIN
FOR POULTRY ("ENROFLOXACIN HEARING")**

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Submission of Data and Information Pursuant to 21 C.F.R. § 12.85

Please find enclosed an original and one copy of Bayer Corporation's submission of data and information pursuant to 21 C.F.R. § 12.85.

Respectfully submitted,

BAYER CORPORATION

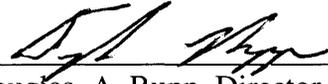
By: _____


Robert B. Nicholas
MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8170
Counsel to Bayer Corporation

00N-1571

CERTIFICATION PURSUANT TO 21 CFR § 12.85(b)

I hereby certify that, to the best of my knowledge and belief, this submission on behalf of Respondent Bayer complies with the requirements of 21 CFR § 12.85, which sets forth the requirements regarding disclosure of data and information by participants of formal evidentiary public hearings.



Douglas A. Rupp, Director
Pharmaceutical Regulatory Affairs
Bayer Corporation

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that an original and one copy of the foregoing Submission of Data and Information Pursuant to 21 C.F.R. § 12.85 was hand delivered, this 22nd day of April, 2002 to:

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

I HEREBY CERTIFY that pursuant to 21 C.F.R. § 12.80(b), a copy of the foregoing transmittal letter and Bayer's Narrative Statement was sent by first class mail, postage prepaid, this 22nd day of April, 2002 to:

Nadine R. Steinberg, Esq.
Center for Veterinary Medicine
U.S. Food and Drug Administration
5600 Fishers Lane
Room 6-57
Rockville, MD 20875

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

I HEREBY CERTIFY that a courtesy copy of the foregoing transmittal letter and Bayer's Narrative Statement was hand delivered this 22nd day of April, 2002 to:

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857



Robert B. Nicholas

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that pursuant to 21 C.F.R. § 12.80(b), a copy of the foregoing transmittal letter and Bayer's Narrative Statement was sent by first class mail, postage prepaid, this 22nd day of April, 2002 to:

Brian Jensen
Royal Danish Embassy
Food, Agriculture and Fisheries Division
3200 Whitehaven Street, N.W.
Washington, DC 20008



Robert B. Nicholas

**NARRATIVE STATEMENT OF RESPONDENT BAYER CORPORATION
PURSUANT TO 21 CFR § 12.85 ON THE PROPOSAL TO WITHDRAW
ENROFLOXACIN (NADA 140-828) FOR USE IN POULTRY**

Respondent Bayer Corporation (“Bayer”) submits this narrative statement of its position on the factual issues in the Notice of Hearing pursuant to 21 CFR § 12.85(b). This statement identifies the type of evidence Bayer intends to introduce to support its position.

INTRODUCTION

Procedural History

The Center for Veterinary Medicine (“CVM”) proposed to withdraw the new animal drug application (“NADA”) for the use of the fluoroquinolone enrofloxacin in poultry, NADA 140-828 (tradename “Baytril”) and issued a Notice of Opportunity for Hearing (“NOOH”). 65 Fed. Reg. 64,954 (October 31, 2000), as amended 66 Fed. Reg. 6623 (January 6, 2001). Bayer requested a hearing on CVM’s proposed withdrawal and presented in support thereof a reply to the NOOH containing an extensive scientific analysis refuting the factual assumptions underlying CVM’s position. (B-1A - February 21, 2002). After an extended review of Bayer’s reply to the NOOH, FDA granted a hearing in this matter. 67 Fed. Reg. 7700 (February 20, 2002).

This matter involves the use of enrofloxacin, a fluoroquinolone antibiotic approved in 1996 by FDA for the treatment of life threatening diseases in chickens and in turkeys. CVM contends that: (1) the use of fluoroquinolones in poultry causes development of fluoroquinolone-resistant *Campylobacter* spp. (a human pathogen) in poultry; (2) these fluoroquinolone-resistant *Campylobacter* spp. are transferred to humans and are a significant cause of the development of fluoroquinolone-resistant

Campylobacter infections in humans; and (3) fluoroquinolone-resistant *Campylobacter* infections in humans are a human health hazard.

Bayer intends to introduce evidence to demonstrate that at the time of approval of enrofloxacin for use in chickens and turkeys CVM was well aware of and relied on data and information indicating (1) that the use of enrofloxacin in chickens and turkeys caused the development of fluoroquinolone-resistant *Campylobacter* in poultry; (2) that these fluoroquinolone-resistant *Campylobacter* are transferred to humans and could be a significant cause of the development of fluoroquinolone-resistant *Campylobacter* infections in humans; and (3) that *Campylobacter* infections (including fluoroquinolone-resistant *Campylobacter* infections) in humans could adversely affect human health. Bayer contends that there is no new evidence showing that enrofloxacin is not safe. To the contrary, to the extent there are new data on resistance since the approval of enrofloxacin, those data further support that the use of enrofloxacin in chickens and turkeys is safe.

Overview of Issues

To understand the significance of these facts, it is important to understand how enrofloxacin is used in chickens and turkeys, the limited number of people potentially affected by poultry related fluoroquinolone-resistant *Campylobacter* infections and the generally non-severe nature of human *Campylobacter* infections.

The use of enrofloxacin in poultry is highly regulated by FDA. Enrofloxacin is used for therapeutic purposes only and NOT used for growth promotion. It is a prescription only product, used under the supervision of a veterinarian, and used only to treat life-threatening diseases. The law prohibits extra label use of enrofloxacin.

Enrofloxacin is not used to treat *Campylobacter* in poultry since *Campylobacter* are not pathogenic to poultry.

The poultry business in the United States is highly concentrated, vertically integrated, and highly mechanized. These birds are raised in “houses,” frequently containing 20,000 or more birds. A poultry production unit may contain many houses. Veterinarians and other professionals closely and regularly monitor poultry health in each house. Once introduced into a house, viral and other diseases rapidly spread throughout the house, infecting the entire house and leaving it vulnerable to bacterial diseases. Once a disease outbreak occurs and birds begin to die from the underlying bacterial infections it is likely that the entire house is already infected, notwithstanding that the birds will exhibit varying degrees of sickness. When used, enrofloxacin is administered to the entire infected house only, to treat the life threatening bacterial diseases infecting the entire house. Enrofloxacin is expensive and therefore used sparingly. Enrofloxacin is used only when there is no alternative. It is used in less than one percent of the 8.6 billion broilers raised annually (2001) and less than 4 percent of the 270 million turkeys raised annually (2000).

The only practical way to treat a flock with enrofloxacin is by water medication. Watering systems in poultry houses are sophisticated. Nipple waterers control the direction and flow of water, and provide the only source of drinking water for the birds. Since sick birds consume relatively large quantities of water, FDA has long accepted water as a safe and effective manner to deliver therapeutic doses of animal drugs, including antibiotics, to poultry.

Poultry processing is also highly automated, though there are differences in the processing of chickens and turkeys. Uniformity is the key to rapid processing of chickens and turkeys and to the economics of the poultry industry. Lower weight birds and sick birds cause delays in the processing lines and equipment can cause gut and other digestive tract ruptures in smaller birds, spilling fecal and cecal contents onto other birds on the production line. Large chilling tanks are used to cool the birds after evisceration, creating the potential to further cross contaminate carcasses with various bacteria. Processing controls, including those mandated in the past few years by the U.S. Department of Agriculture (“USDA”) under the Hazard Analysis Critical Control Point Program (“HACCP”) have significantly reduced bacterial carcass loads; including dramatic reductions in *Campylobacter* on poultry.

Campylobacter are commensal organisms in many animals, including poultry, and are ubiquitous in the environment. People can become infected with *Campylobacter* from many sources including foreign travel, raw and swimming water, pets, domestic animals, consumption of a variety of foods, and other people. Poultry consumption has long been believed to be a major source of infections in humans, through the consumption of undercooked chicken and by cross contamination of cutting boards and other surfaces by raw poultry juices. *Campylobacter* do not grow on raw poultry but need specific conditions to multiply including very low oxygen atmospheres and high CO₂ atmospheres.

A randomly occurring point mutation in a single gene in *Campylobacter* rapidly leads to fluoroquinolone resistance in the *Campylobacter*. Treatment of people and animals with fluoroquinolones can exert a selection pressure that leads to the elimination

of *Campylobacter* that are susceptible and the survival and multiplication of *Campylobacter* that are resistant. Additional selection pressures can come from other chemicals in the environment and poultry flocks that have never been treated with enrofloxacin or any other fluoroquinolone have been found to be colonized by fluoroquinolone-resistant *Campylobacter*. To the extent poultry is believed to be a significant source of *Campylobacter* infections in humans, there is no reason to believe that poultry could not also be a source of fluoroquinolone-resistant infections in humans, although the amount of poultry's contribution to fluoroquinolone-resistant *Campylobacter* infections in humans is significantly less than that estimated by CVM.

Campylobacteriosis, the human disease caused by some infections with *Campylobacter*, is a typical foodborne gastrointestinal illness, typically lasting 5-10 days and causing fever, diarrhea, and abdominal pain. *Campylobacter* is well recognized to be associated with several rare complications. Campylobacteriosis is almost always self-limiting; the vast majority of people do not seek medical care. For the small percentage that do, antibiotics are generally not necessary, not given, and may be contraindicated. If not initiated early, patients frequently recover before antibiotic treatment can have an effect. Fluoroquinolones are contraindicated (and not approved for use) in several groups of patients, including infants who comprise in excess of 27 percent of all patients with campylobacteriosis. Campylobacteriosis can be more serious in a very small percentage of patients, generally those with weakened immune systems, such as chemotherapy and organ transplant patients and those with HIV-AIDS. For these patients, antibiotic treatment may be indicated. Macrolides and fluoroquinolones are generally considered the drugs of choice. Since early antibiotic treatment may lessen the duration of the

disease, physicians sometimes treat without determining the genus of the infective agent and its susceptibility to specific antibiotics (i.e. empiracally), even when antibiotics may be unnecessary.

Empiric treatment of campylobacteriosis can fail if the bacteria are clinically resistant to the chosen antibiotic, but treatment of strains that are resistant to ciprofloxacin on *in vitro* tests have not been regularly associated with clinical failure. Infectious disease specialists are knowledgeable in the expected consequences of failure and would expect the possibility of extended duration of disease and perhaps enhanced virulence.

All of the above facts were known to CVM in October 1996, when FDA approved enrofloxacin for use in chickens and turkeys.

Since approval,

- per capita chicken consumption has increased;
- the incidence of campylobacteriosis has markedly dramatically decreased;¹
- studies indicate that poultry as a source of human *Campylobacter* infections has been greatly overestimated;
- the percent of fluoroquinolone-resistant *Campylobacter* isolates, both human and poultry, collected in the National Antimicrobial Resistant Monitoring System (“NARMS”), the government’s monitoring program, has remained stable notwithstanding the fact that use of enrofloxacin in turkeys and chickens has increased;

¹ Last week CDC reported that the incidence of campylobacteriosis has decreased 27 percent from 1996 to 2001. CDC, Morbidity and Mortality Weekly Report, April 19, 2002. During this period government surveillance and attention to foodborne illness has increased.

- patients with *Campylobacter* that have been determined to be resistant to fluoroquinolones by an *in vitro* test have been shown to respond to treatment with fluoroquinolones.
- no clinical breakpoint for fluoroquinolones has been determined for *Campylobacter*. (The breakpoint is the point dividing susceptible and resistant populations of *Campylobacter*, expressed as µg/ml. The breakpoint is useful in helping to determine whether an isolate is resistant or susceptible to a particular antibiotic.)
- the vast majority of *Campylobacter* infections are not resistant.
- no serious adverse human health consequences have been demonstrated as a result of primary fluoroquinolone-resistant *Campylobacter* infections.

Accordingly, Bayer has concluded that enrofloxacin use in chickens and turkeys is safe.

BACKGROUND

The Narrative Statement submitted by the CVM proposes to withdraw approval of the NADA for use of the fluoroquinolone enrofloxacin in chickens and turkeys, NADA 140-828. It cites section 512(e)(B)(1) of the Federal Food, Drug and Cosmetic Act as the basis for withdrawing the approval for enrofloxacin. That section provides for withdrawal of a NADA upon finding:

That *new evidence* not contained in such application or not available to [FDA] until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to [FDA] when the application was approved, *shows* that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved...

21 U.S.C. § 360b(e)(1)(B) (emphasis added).

Thus, it is clear that FDA bears the initial burden to come forward with “new evidence” that “shows” that an approved drug is not now shown to be safe for its intended use before such an approval may be withdrawn. 21 U.S.C. § 360b(e)(1)(B). The D.C. Circuit in *Rhone-Poulenc* has described FDA’s burden as:

whether the FDA has presented new evidence raising questions about the safety of [the drug] that are *sufficiently serious* to require the manufacturers to demonstrate that [the drug] is safe.

Rhone-Poulenc, Inc. v. FDA, 636 F.2d 750, 752 (D.C. Cir. 1980) (emphasis added). Bayer’s position is that in order to withdraw the approval for enrofloxacin, CVM must come forward with “new evidence” that demonstrates (“shows”) that there is a reasonable basis *seriously* to question enrofloxacin’s safety.

Both CVM’s and Bayer’s § 12.85 submissions demonstrate that the debate surrounding the use of antimicrobials in food animals, involving sub-therapeutic as well as therapeutic uses has been ongoing for decades. The issues and sub-issues raised by CVM for this hearing -- whether human use antibiotics should also be used in food animals; whether antibiotic use will result in the emergence of resistant organisms in such food animals; whether resistant organisms will be transferred to humans who consume the foods of animal origin; whether such transferred organisms will make people sick; and whether human treatment will ultimately be compromised -- have been the central issues in the debate for decades.

Not only have these questions been posed about use of antibiotics in food animals generally, but prior to enrofloxacin approval these questions were posed about the use of fluoroquinolones specifically. As part of its regulatory process of fluoroquinolone approvals, in May 1994 FDA took an unprecedented step and brought together

government and non-government experts in antibiotic use and resistance from human and veterinary medicine for a joint meeting of the CVM's Veterinary Medicine Advisory Committee and the Center for Drug Evaluation and Research's Anti-Infective Drugs Advisory Committee. This Joint Advisory Committee was specifically convened "in response to concerns that approval of fluoroquinolone drugs for use in food animals may result in increased development of fluoroquinolone resistance in zoonotic organisms harbored by food animals that are transmitted to humans and cause disease." 61 Fed. Reg. 353 (Jan. 4, 1996). Concern was expressed at the joint advisory committee meeting, and data was presented, about the development of fluoroquinolone-resistant *Campylobacter* in poultry, transfer of fluoroquinolone-resistant *Campylobacter* to humans and adverse health impacts arising from the inability of treating campylobacteriosis with fluoroquinolones. After the 1994 public hearing, the Joint Advisory Committee unanimously decided that fluoroquinolones could be used in food producing animals with certain limitations. *Id* and G-818 at 4. The Joint Advisory Committee suggested that: the drugs be limited to prescription use, resistance be monitored and measures be taken to assure appropriate dosing (including strict approval requirements, educational measures for users and use restrictions such as prohibiting extra-label use). G-818 at 41.

Following the suggestions of the Joint Advisory Committee, CVM approved enrofloxacin limited to prescription use in chickens and turkeys and subject to restrictions and post-approval monitoring of resistance. The intent to withdraw the approval of enrofloxacin for poultry suggests that CVM now believes that there have been unanticipated consequences caused by the approval of enrofloxacin and that, therefore, these measures have failed. Bayer intends to introduce evidence that these measures are,

in fact, working and that nothing unexpected has happened since enrofloxacin was approved. In fact, available data since the approval show that enrofloxacin is safe.

The historical record contained in both parties' submissions supports Bayer's position that there is no new evidence that shows that enrofloxacin is not now shown to be safe for use under the limited conditions of use upon which the application was approved.

ISSUES FOR HEARING

Whether there is a reasonable basis from which serious questions about the safety of enrofloxacin use in poultry may be inferred?

Whether enrofloxacin use in poultry acts as a selection pressure, resulting in the emergence and dissemination of fluoroquinolone-resistant *Campylobacter* spp. in poultry?

CVM contends that the use of enrofloxacin in poultry has resulted in a significant and unexpected rise in fluoroquinolone-resistant *Campylobacter* spp. in poultry. It intends to support this contention by producing evidence on *Campylobacter* colonization in poultry; enrofloxacin use in poultry; the biological process of selection pressure leading to the emergence and dissemination of fluoroquinolone-resistant *Campylobacter*; lab tests showing the rapid emergence of fluoroquinolone-resistant *Campylobacter* when poultry colonized with *Campylobacter* have been treated with enrofloxacin; sensitivity testing of *Campylobacter* isolated from poultry.

Bayer will introduce evidence that none of these facts constitute "new evidence." Bayer's evidence will show that the biological principle of selection pressure was known by CVM prior to the approval of enrofloxacin and that CVM has no new evidence that the issue of fluoroquinolone-resistant *Campylobacter* in chickens or turkeys is more significant now than at the time of approval of enrofloxacin. While the use of

enrofloxacin in chickens and turkeys may result in some measure of selection pressure, the data at the time of approval demonstrated that CVM was well aware that the use of enrofloxacin in chickens and turkeys exerts selection pressure that leads to fluoroquinolone-resistant *Campylobacter*. Evidence since then demonstrates that the level is not higher than expected, not significant, and that the ultimate impact has been overstated by CVM. In fact, levels of *Campylobacter* on chicken carcasses are decreasing and the level of resistance on chicken carcasses has been stable since this data was first collected. In short, there is no new evidence that the issue of selection pressure raises concerns that were not anticipated when enrofloxacin was approved in 1996.

Bayer will introduce evidence at the hearing, including expert testimony, scientific papers, and studies demonstrating the following:

1. The biological principle of microbial mutation and selection, applicable to the use of any antimicrobial, has long been well known in the scientific community; at the time of approval of enrofloxacin for use in poultry, FDA was well aware that enrofloxacin and other fluoroquinolone use exerted a selection pressure on *Campylobacter* to produce resistant populations.
 - Selection pressure varies based on a variety of factors. These include the type of antimicrobial used, the number of individuals treated, the dosage regimen, the duration of treatment, and the overall extent of use in the population at risk
 - Enrofloxacin is not the only selection pressure that acts upon *Campylobacter*. Fluoroquinolone-resistant *Campylobacter* are naturally present in the environment and are found in poultry even where flocks have not been treated with fluoroquinolones.

- The use of fluoroquinolones to treat *Campylobacter* infections in humans exerts very significant selection pressure, so that fluoroquinolone-resistant *Campylobacter* isolated from humans can in fact merely reflect use of a fluoroquinolone to treat infections in humans.
2. The fact that chickens that harbor *Campylobacter* quickly develop fluoroquinolone-resistant *Campylobacter* once a fluoroquinolone is administered in laboratory conditions was well known by FDA at the time of approval.
 - Prior to the approval of enrofloxacin there was evidence from laboratory studies that chickens that harbor *Campylobacter* quickly develop fluoroquinolone-resistant *Campylobacter* once a fluoroquinolone is administered. More recent laboratory studies merely reach the same result and are not new evidence.
 - Nevertheless, these laboratory results do not take into account possible recolonization of susceptible *Campylobacter* in the field, nor the pathogen load at slaughter. Under real world conditions, selection pressure may be lower due to different dosing regimens, different colonization rates, and the fact that susceptible *Campylobacters* can colonize, dominate and displace the resistant ones.
 - Furthermore, evidence shows that even under laboratory conditions resistance does not always persist, especially where lower, but still approved, doses are administered. In the field, other factors may govern the persistence of fluoroquinolone resistance, among them the re-introduction of new, fluoroquinolone-sensitive strains superseding the resistant strains.
 3. There are no recommended antibiotic breakpoint concentrations for *Campylobacter* isolated from turkeys or chickens. Data have instead been

analyzed with reference to ciprofloxacin breakpoints of the NCCLS for bacteria other than *Campylobacter* spp. Therefore *Campylobacter* isolates classified as “resistant” *in vitro* may not actually be clinically resistant.

4. Despite a high prevalence of *Campylobacter* in the environment, *Campylobacter* loads on chicken carcasses are decreasing.
 - *Campylobacter* are ubiquitous in the environment including in streams, and colonize numerous animals including pets such as dogs and cats as well as domesticated and wild mammals, birds, flies and other animals.
 - Despite evidence that *Campylobacter* are naturally present in large numbers in the environment, both the prevalence and carcass pathogen load of chickens infected with *Campylobacter* is decreasing due to HACCP and other factors.
 - Evidence shows that not only do *Campylobacter* not multiply outside the chicken gut, but the level of *Campylobacter* is frequently reduced post-slaughter due to refrigeration/freezing or entirely eliminated due to further processing (including cooking).
5. NARMS data show that fluoroquinolone resistance rates for *Campylobacter* isolated from chicken have remained stable during the data collection period. This rebuts FDA’s assertion that poultry isolate resistance is rising as a result of use of enrofloxacin in poultry.
 - According to data from the NARMS, the percent resistance for *Campylobacter* isolates recovered from chicken carcasses has remained stable at approximately 10% since 1998, the period when NARMS first started to collect *Campylobacter* isolates from chickens.

- The NARMS data have flaws, however, and these flaws lead one to conclude that the 10% figure is actually an overestimation of the total resistance level. For example, the isolation method of selective enrichment likely introduces bias.
6. Fluoroquinolones are used in an extremely small percentage of the total chicken broiler population. Of the 8.6 billion broilers produced in the United States in the year 2001, less than one percent had been medicated with enrofloxacin. Of the 270 million turkeys produced in the United States in the year 2000, less than four percent were treated with enrofloxacin. It is not plausible that fluoroquinolone-resistant *Campylobacter* in human isolates is significantly caused by the use of enrofloxacin in chickens and turkeys.
 7. *Campylobacter jejuni*, the organism believed responsible for 99% of all reported campylobacteriosis cases in humans is found primarily in chickens while *Campylobacter coli* is found primarily in turkeys. FDA has presented no evidence that resistant *C. jejuni* infections in humans are occurring as a result of use of enrofloxacin in turkeys.

Whether fluoroquinolone-resistant *Campylobacter* spp. in poultry are transferred to humans and whether they contribute to fluoroquinolone-resistant *Campylobacter* infections in humans?

CVM contends that fluoroquinolone-resistant *Campylobacter* in poultry are transferred to humans and are a significant cause of fluoroquinolone-resistant *Campylobacter* infections in humans. CVM's position is alleged to be supported by the following facts: *Campylobacter* are commonly found in poultry; campylobacteriosis is a common foodborne illness which may be severe; risk of campylobacteriosis, including from fluoroquinolone-resistant *Campylobacter*, is strongly associated with exposure to

poultry, including handling, consumption and cross-contamination. CVM has stated it intends to introduce the following evidence to support its position: poultry consumption data; epidemiologic studies finding a strong association between eating poultry and acquiring both *Campylobacter* infections and fluoroquinolone-resistant *Campylobacter* infections; studies linking the genetic make up of *Campylobacter* isolates in humans and poultry; the temporal relationship between the approval of fluoroquinolones for use in poultry and the rise of fluoroquinolone-resistant *Campylobacter* infections in humans in the U.S. and in other countries; the biological implausibility that U.S. human fluoroquinolone-resistant *Campylobacter* infections are entirely due to use of fluoroquinolones in humans or to spread from person-to-person; a risk assessment showing that a portion of fluoroquinolone-resistant *Campylobacter* infections is attributable to use of fluoroquinolones in poultry. Bayer's position is that the risk of fluoroquinolone-resistant *Campylobacter* infections in humans was known to, and considered by, CVM prior to the 1996 approval of enrofloxacin for use in chickens and turkeys. There is no evidence that the risk of fluoroquinolone-resistant *Campylobacter* infections in humans in the United States poses a greater hazard to public health than was anticipated when enrofloxacin was approved in 1996. Bayer's position is that CVM has overestimated substantially the role of chicken as a source of *Campylobacter* infection overall (and particularly of domestically acquired fluoroquinolone-resistant *Campylobacter* infections).

Bayer intends to introduce evidence on the issue of *Campylobacter* transfer separately for chickens and turkeys. Enrofloxacin was approved for the control of mortality in chickens associated with *E. coli* organisms, as well as for the control of

mortality in turkeys associated with *E. coli* and *Pasteurella multocida* organisms. Bayer was required by FDA to submit data separately demonstrating in chicken and turkey the safety and efficacy of enrofloxacin. If enrofloxacin was not shown to be safe in chickens, there would be no reason to revoke the approval for its use in turkeys unless it was also not shown to be safe for that use.

Bayer does not dispute that fluoroquinolone-resistant *Campylobacter* spp. from chickens and turkeys can be transferred to humans. Bayer does dispute the extent and significance of any such transfer and whether fluoroquinolone-resistant *Campylobacter* from chickens and turkeys are a significant cause of fluoroquinolone-resistant *Campylobacter* infections in humans.

Bayer will introduce evidence at the hearing, including expert testimony, scientific papers, and studies demonstrating the following:

1. Taken as a whole, data from foreign countries comparing dates of poultry fluoroquinolone approval, and use, with rates of fluoroquinolone resistance in human isolates do not support claims of a causal relationship (nor even a temporal relationship) between fluoroquinolone approval for use in poultry and an increase in human isolate *Campylobacter* fluoroquinolone-resistance.
2. In the United States, any purported temporal association between enrofloxacin approval and fluoroquinolone-resistant *Campylobacter* infections in humans is belied by data demonstrating appreciable quinolone and fluoroquinolone resistance in human *Campylobacter* isolates prior to 1996.
3. Additionally, U.S. data on annual per capita chicken consumption and annual campylobacteriosis incidence rates also belie any causal relationship between chicken

and *Campylobacter* infection transmission to humans. While per capita chicken consumption is increasing, campylobacteriosis incidence rates are simultaneously decreasing.

4. Many of the epidemiology studies relied on by CVM to show that chicken is a significant source of campylobacteriosis are outdated and invalid. Much newer case-control study data from the Centers for Disease Control and Prevention (CDC) do not demonstrate a strong correlation between chicken factors (including chicken consumption) and the risk of acquiring *Campylobacter* infections. A comprehensive analysis of data generated from CDC's recent *Campylobacter* case-control study shows that CVM has overstated the role that consumption of poultry plays as a risk factor for human campylobacteriosis. This analysis shows that in fact domestically produced poultry are not a significant cause of *Campylobacter* infections in humans.
5. National surveillance program monitoring data (including data from human feces isolates, chicken carcass isolates and retail product chicken isolates) do not show a significant increase in either human-origin fluoroquinolone-resistant *Campylobacter* isolates or chicken-origin fluoroquinolone-resistant *Campylobacter* isolates since enrofloxacin's 1996 chicken and turkey use approvals. NARMS human isolate data, when analyzed in the proper context, demonstrate that resistance in human *Campylobacter* isolates has remained relatively stable despite the continued use of enrofloxacin in chickens and turkeys. Additionally, although NARMS chicken data indicate that broiler carcasses sampled at slaughter houses are contaminated with *Campylobacter* organisms and that a percentage of those organisms may be fluoroquinolone resistant, the percentage of resistant isolates has remained low and

stable over the sampling years despite the use of enrofloxacin in chickens over that time period. Moreover, the NARMS system does not provide data that can be interpreted as a representation of general patterns for the entire United States, nor does it address whether there is a causal link between emergent animal resistance and emergent human resistance. Finally, because of differences in sampling patterns from year to year, data on *Campylobacter* and antimicrobial resistance patterns from year to year cannot meaningfully be compared.

6. Studies comparing the genetic composition of *Campylobacter* from chicken isolates and human isolates do not demonstrate that chicken is a significant source of human *Campylobacter* infections. The most rigorous studies show a range of 3% to 20% overlaps of clonally related *Campylobacter* strains isolated from chicken with those isolated from humans. This means that 80% to 97% of the *Campylobacter* found in human isolates are not the same as those found in chickens (or turkeys). Moreover, there are no studies tracing directly the route of exposure from chickens or turkeys to humans. Even the best studies employing molecular genetic typing and case/control data use chicken (or turkey) isolates and human isolates from different time frames. Thus, a causal connection between chickens (or turkeys) and human infection cannot be drawn. Additionally, a common source of infections for the two populations, such as environmental sources, cannot be excluded.
7. The predominant *Campylobacter* species in chicken is *C. jejuni* while that in turkeys is *C. coli*.
8. In addition to use of fluoroquinolones to treat *Campylobacter* infections in humans and person to person transmission of *Campylobacter*, foreign travel, ownership of

pets, drinking of unpasteurized milk, drinking raw water, swimming water, consumption of non-poultry foods of animal origin, and other causative factors are strongly associated with people being infected with *Campylobacter*, including potentially fluoroquinolone-resistant *Campylobacter*.

9. The Vose risk assessment used by CVM to attempt to quantify the human health impact of fluoroquinolone use in chickens is not a valid risk assessment generally, or for assessing the public health impact of fluoroquinolone use in poultry. It does not follow most of the generally accepted standards for a risk assessment; it has no historical or predictive value; available real data (as opposed to the model's assumptions) do not validate the model, and is not valuable as a risk management tool. The Vose assessment greatly overestimates the extent to which chicken is a source of *Campylobacter* infection overall (and particularly of fluoroquinolone-resistant *Campylobacter* infections) for a number of reasons. For example, variable P_{ca} , the chicken-associated cases, uses selective data from outdated studies instead of CDC's more recent case/control studies. Vose's estimated value P_{rh} , the proportion of *Campylobacter* infections from chicken that are fluoroquinolone resistant, of over 20% is far larger than the upper 95% confidence limit for its value, based on the data cited in the risk assessment. P_c , the total prevalence of *Campylobacter*, does not take into consideration data showing reduced prevalence of *Campylobacter*. Additionally, in variable P_{fq} , the risk assessment assumes that fluoroquinolone resistance in one or more *Campylobacter* isolates implies 100% ineffective fluoroquinolone treatment despite articles to the contrary. Also, the Vose estimate of the nominal mean chicken acquired *Campylobacter* cases (λ_{2T}) fails to remove infants and young children from

the population considered as candidates for ineffective fluoroquinolone treatment, despite the fact that children are not treated with fluoroquinolones.

10. Neither Vose nor any other risk assessment conducted by CVM attributes any adverse human health impact to the use of enrofloxacin in turkeys.

Whether fluoroquinolone-resistant *Campylobacter* infections in humans have the potential to adversely affect human health?

CVM's position is that the development of fluoroquinolone-resistant *Campylobacter* has the potential to adversely affect human health. In support of its position CVM asserts that (1) to be effective in treating campylobacteriosis, treatment with an antibiotic must begin early; (2) if treatment is not initiated early, disease may be prolonged or result in complications; (3) fluoroquinolones traditionally have been effective when used by physicians to empirically treat foodborne illnesses.

Bayer's position is that the potential adverse human health effect of *Campylobacter* infections in humans, and of fluoroquinolone-resistant *Campylobacter* infections in humans, was known to, and considered by, CVM prior to the 1996 approval of enrofloxacin for use in chickens and turkeys. There is no new evidence that the potential adverse health affect of fluoroquinolone-resistant *Campylobacter* infections in humans poses a greater hazard to public health than was anticipated at the time of enrofloxacin's 1996 approval. In fact, new data support that there are no unexpected potential adverse health impacts from use of enrofloxacin in chickens and turkeys. Bayer's position is that any potential adverse human health effects of fluoroquinolone-resistant *Campylobacter* infections overall (and particularly of chicken and/or turkey related, domestically acquired fluoroquinolone-resistant *Campylobacter* infections) is

substantially overestimated by CVM in terms of numbers of persons affected and the severity of the potential adverse health hazard.

Bayer will introduce evidence at the hearing, including expert testimony, scientific papers, and studies demonstrating the following:

1. Campylobacteriosis has been well known and recognized as a major foodborne illness causing gastroenteritis since the 1980s, long before the approval of enrofloxacin in October 1996.
 - *Campylobacter jejuni*, the organism believed responsible for 99% of all campylobacteriosis cases, causes an illness characterized by diarrhea, generally lasting 5 to 10 days, fever, abdominal pain, nausea, headache and muscle pain.
 - Campylobacteriosis is almost always a self-limiting disease, meaning that symptoms will resolve without need for any antimicrobial treatment.
 - Significant complications of campylobacteriosis, such as Guillain- Barre Syndrome have long been understood as very rare.
 - The increased potential seriousness of campylobacteriosis in immune-compromised individuals such as chemotherapy patients, organ transplant patients, and HIV-AIDS patients has also been well-recognized for many years before enrofloxacin approval for use in chickens and turkeys and constitutes a very small percentage of total infections.
 - The total number of *Campylobacter* infections have declined 27% over the past 5 years.
 - Approximately 27.5% of all *Campylobacter* infections occur in infants and an undetermined number of infections occur in older children

2. Treatment for campylobacteriosis has also been well understood medically long before the approval of enrofloxacin for use in chickens and turkeys.
- The vast majority of people with campylobacteriosis do not seek medical treatment.
 - For the small number of people who do seek medical treatment, antibiotics typically are either unnecessary or not indicated. The CDC and FDA agree most infections are not treated with antibiotics.
 - Acute gastrointestinal disease is normally treated supportively with fluids. Only in very severe cases will antibiotic treatment be initiated before results of stool-cultures are available.
 - Macrolides, an alternative class of antibiotics to which *Campylobacter* remain highly susceptible, are the preferred treatment for campylobacteriosis and are an alternative treatment for an infection that is clinically resistant to treatment with fluoroquinolones.
 - Since a substantial percentage of gastrointestinal illnesses in humans are viral in origin, not bacterial in origin, an antibiotic will be of no medical benefit. Empiric treatment may also cause development of resistant organisms in the patient.
 - *E. coli* causes an increasing number of severe foodborne enteritis cases. In these cases, antibiotic treatment is contraindicated. Starting an empiric treatment with an agent effective against *E. coli*, such as a fluoroquinolone, may jeopardize the life of the patient due to concerns of Hemolytic Uremic Syndrome.

- Development of new, rapid *Campylobacter* assays have been reported which can be used to assess whether the causative agent is *Campylobacter* spp. or not. Such tests can be useful in treating patients with severe and complicated acute enteritis.
 - Fluoroquinolones are contraindicated, and not approved for use in children, and therefore not used for treatment of fluoroquinolone-resistant infections in children.
 - Data show that people suffering from Guillain-Barre Syndrome who have previously suffered from a *Campylobacter* infection frequently have been asymptomatic for the *Campylobacter* infections. In such cases, there would have been no reason to prescribe an antibiotic for treatment of campylobacteriosis.
3. At the time of approval, and long before, FDA understood that a fluoroquinolone-resistant *Campylobacter* infection could lead to the inability to treat campylobacteriosis with a fluoroquinolone and might result in a longer duration of symptoms or additional complications.
- In immunocompromised individuals, (i.e., those patients most at risk for systemic infections) rapid development of fluoroquinolone-resistant *Campylobacter jejuni* from treatment with fluoroquinolones, makes other classes of antibiotics or combination therapy preferable.
4. Data do not demonstrate either a longer duration of illness or greater extent of complications for infections that are caused by fluoroquinolone-resistant *Campylobacters*.

5. No protective effect of antibiotic treatment in acute campylobacteriosis on the subsequent development of complications has been demonstrated nor has the susceptibility of *Campylobacter jejuni* been related to the frequency of complications.
 - Evidence suggests that the duration and potential for additional complications due to campylobacteriosis infections are the same regardless of whether it is caused by a resistant or susceptible *Campylobacter jejuni*.
 - There are no data to indicate that antibiotic treatment, including fluoroquinolone treatment, reduces the possibility of further complications from the infection.
6. Data suggest that fluoroquinolones may remain an effective clinical treatment even when the *Campylobacter jejuni* is determined to be resistant to fluoroquinolones by *in vitro* testing.
 - Clinical breakpoints have not been established to distinguish between resistant and susceptible populations of *Campylobacter jejuni* based on clinical response.
 - Pharmacokinetic data show high gut concentrations are achieved suggesting that clinical efficacy may be obtained even when *in vitro* testing suggests “resistance.”
7. *Campylobacter jejuni*, the organism believed responsible for 99% of all campylobacteriosis cases, is predominately found in chickens and not turkeys. FDA has presented no evidence that fluoroquinolone-resistant *Campylobacter*

jejuni infections in humans are occurring as a result of enrofloxacin use in turkeys and present any adverse health consequence.

Whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe?

Bayer's position is that after consideration of the relative risks and benefits of enrofloxacin, there can be no doubt that the drug is safe under the approved conditions of use in chickens and turkeys.

Under relevant D.C. Circuit precedent, the issue of safety must include an evaluation of risks and benefits to human health, animal health, the environment, and the economy. Bayer believes that consideration of the general safety of enrofloxacin must also take into account possible alternative patterns of restricted use that would eliminate or mitigate potential risks.

Bayer will introduce evidence at the hearing, including expert testimony, scientific papers, and studies demonstrating the following:

1. Use of enrofloxacin in chickens and turkeys has a substantial and quantifiable human health benefit that outweighs the purported risks of enrofloxacin use. For example, enrofloxacin is the only effective treatment for *E. coli* complicated air sacculitis in broilers. Broilers with air sacculitis lesions are significantly less uniform which results in more breaches of gut integrity of smaller birds during processing. Such broilers have higher levels of fecal contamination as demonstrated by higher *Campylobacter*, *Salmonella* and *E. coli* colony enumeration on carcasses at processing. Therefore, the use of enrofloxacin to treat respiratory *E. coli* infections such as air sacculitis in broilers results in healthier birds entering broiler-processing plants. Removal of enrofloxacin from the market would result in more fecal

contamination when untreated air sacculitis flocks are processed. This will lead to a higher foodborne pathogen load on carcasses, presenting a greater risk to the consumer of acquiring *Salmonella*, *E. coli*, *Campylobacter* and other pathogens from improperly handled chicken.

2. Use of enrofloxacin in chickens and turkeys has substantial and quantifiable animal health and welfare benefits that outweigh the purported risks of enrofloxacin use. Animals, including chickens and turkeys, deserve to be treated with effective therapies when they become sick, just as humans deserve treatment when they become ill. The nervous system of the chicken and turkey is capable of feeling pain, and disease left untreated causes suffering and death in these populations. Veterinarians are responsible for treatment decisions for animals and should have effective drugs available for use in animal populations in a judicious manner.
3. Withdrawal of enrofloxacin for use in chickens and turkeys will have an adverse environmental impact that is not outweighed by the purported risks of enrofloxacin use. For example, absent an effective therapy, respiratory disease in chickens and turkeys will result in increased mortality. Disposal of dead birds in deep, unlined pits or by incineration could result in higher coliform counts in ground water, and reduce air quality. Increased mortality will result in the need to increase production head count requiring the building of more poultry houses, further taxing land and water resources. Additionally, absent an effective air sacculitis treatment, flocks will have higher feed conversions; more feed will need to be grown, so more nitrogen and phosphorous fertilizers will need to be applied to agricultural lands and reprocessing of birds with air sacculitis will require more water resources.

4. Withdrawal of enrofloxacin for use in chickens and turkeys will have an adverse economic impact on the broiler and turkey production industry, as well as the chicken and turkey consuming public, that is not outweighed by the purported risks of enrofloxacin use. The economic harm to both the chicken broiler industry and turkey industry is well in excess of \$100 million annually each if enrofloxacin is removed from the market.
5. Mitigation measures (short of withdrawal of enrofloxacin) exist that, if put into place, would reduce further the potential risk of fluoroquinolone-resistant *Campylobacter* transmission to humans while keeping enrofloxacin available to safeguard animal health.
6. The risk FDA seeks to eliminate by withdrawing enrofloxacin for use in poultry is, even by FDA's own calculation, less than that accepted for microbiological contamination of bottled drinking water. That standard was set based on *Cryptosporidium*, a very significant human pathogen.
7. Withdrawal of enrofloxacin for use in poultry will have no appreciable benefit to human health. Action by USDA and the food processing industry to reduce microbial contamination of food products of animal origin, prudent use of antibiotics by producers and veterinary and human medicine doctors, and proper cooking by consumers and food producing establishments will have a far greater impact on the potential problem.

CONCLUSION

CVM, as the party who bears the burden of proof, is required to present new evidence that raises serious questions about the ultimate safety of the product before the burden

shifts to Bayer to demonstrate the product is safe. Though CVM need not do so with absolute certainty, its basis must be sound and supported by the evidence. This careful balance has been expressed by the FDA Commissioner's decision involving Cyclamate.

In it the Commissioner states:

[The Sponsor] also contends that, for a scientist to conclude that cyclamate has not been shown to be safe there must be an "objective basis for the evaluation of the data presented" ... I agree.

It is not possible, however, to provide a formula specifying precisely the quantity and quality of evidence an applicant is required to submit in order to meet its burden. But the lack of a precise formula does not mean that the process lacks objectivity. Nor does a lack of certainty mean a lack of objectivity, especially where the subject matter is complex and the science evolving. The requirement of objectivity is met, I believe, if the agency reviews the evidence carefully, conducts a fair evaluation of the evidence, states its reasons for crediting or not crediting a piece of evidence, weighs all the evidence, applies the correct statutory standards, and decides.

Cyclamate (Cyclamic Acid, Calcium Cyclamate, and Sodium Cyclamate), Final Decision Following a Formal Evidentiary Public Hearing, 45 Fed. Reg. 61,474 (Sept. 16, 1980). Bayer acknowledges the complex nature of this discussion and the seriousness of the issue, but submits that a careful, fair and objective review of the evidence demonstrates that CVM has not met its burden of proof and that enrofloxacin was, is, and remains safe for its intended use.

BAYER'S § 12.85 SUBMISSION INDEX

Exhibit No.	Author	Title
B-1(A)		Submission of Facts, Information and Analyses in Response to the Notice of Opportunity for Hearing
B-1(B)		Additional Analysis in Response to the Notice of Opportunity for Hearing
B-1	Aarestrup, F. M., E. M. Nielsen, M. Madsen and J. Engberg	1997. Antimicrobial susceptibility patterns of thermophilic <i>Campylobacter spp.</i> from humans, pigs, cattle, and broilers in Denmark. <i>Antimicrob. Agents Chemother.</i> 41:2244-2250
B-2	Adler-Mosca, H. and M. Altwegg	1991. Fluoroquinolone resistance in <i>Campylobacter jejuni</i> and <i>Campylobacter coli</i> isolated from human faeces in Switzerland. <i>J. Infect.</i> 23:341-342
B-3	Agriculture Canada	1999. Industry statistics, p. 111-113. <i>In Canada's Who's Who of the Poultry Industry 1999</i>
B-4	Ahmed, H.; H. Hariharan and C. Yason	1992. Drug resistance and toxigenic properties of <i>Campylobacter jejuni</i> from broiler chicken, p. 469. <i>In Proceedings of Canadian Veterinary Convention.</i> Prince Edward Island, Charlottetown
B-5	Angulo, F.	January 2001. Personal communication
B-6	Anonymous	2000. DANMAP 99. Consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from animals, food and humans in Denmark, p. 24-28. Danish Zoonosis Centre, Copenhagen, Denmark
B-7	Anonymous	September 20, 1996. NADA 140-828, Baytril Poultry Environmental Assessment submitted by Bayer, on file with FDA
B-8	Anonymous	September 20, 1996. NADA 140-828, Safety and Efficacy Studies submitted by Bayer, on file with FDA
B-9	Anonymous	1995. Table 4-2, p. 31. <i>In Process Design Manual for Land Application of Sewage Sludge and Domestic Seepage.</i> EPA/625/R-95/001
B-10	Anonymous	CDC Online, " <i>Campylobacter</i> Infections". Located on the CDC website at: http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm .
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B-15	Blaser, M.; D. Taylor and R. Feldman	1983. Epidemiology of <i>Campylobacter jejuni</i> infections, p. 157-176. In Epidemiologic reviews, vol. 5. Johns Hopkins University School of Hygiene and Public Health
B-16	Blaser, M.; F. La Force; N. Wilson and W. L. L. Wang	1980. Reservoirs for human campylobacteriosis. J. Infect. Dis. 141:665-669
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B-949	Heidi Kassenborg	4/2/02 memo to M. Vaughn re: questions on data
B-950	Showmedvm@aol.com	11/10/01 memo to M. Vaughn re: 2000 per capita poultry consumption
B-951	Kirsten Volmer	9/10/01 memo to M. Vaughn re: Demark, etc.
B-952	Robert Walker	11/17/01 memo to M. Vaughn re: OR Study Protocol
B-953	Kirk Smith	1/9/02 memo to M. Vaughn re: jejuni/coli/data
B-954	N. Stern	12/18/00 memo to M. Vaughn re: 2 references that document the increase of campylobacters on the carcasses during transport from the farm to the processing plants, etc.
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B-984	R.J. Bywater	Sense and Nonsense in Surveillance Programs, p. 118-127. Edited by Goran Hugoson and Catarina Wallen in <i>Acta Veterinaria Scandinavica - A Quarterly Research Journal - Proceedings of the Symposium on Antibiotic Resistance with Emphasis on Animal-Human Transfer. Supplementum 93</i>
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B-986	Heinz-Georg Wetzstein; Marc Stadler; Hans-Volker Tichy; Axel Dalhoff; Wolfgang Karl	Degradation of Ciprofloxacin by Basidiomycetes and Identification of Metabolites Generated by the Brown Rot Fungus <i>Gloeophyllum striatum</i> . <i>Applied and Environmental Microbiology</i> , Apr. 1999, Vol. 65, No. 4, p. 1556-1563
B-987		Sales Of Antimicrobial Products Used As Veterinary Medicines, Growth Promoters and Coccidiostats In The UK In 2000, 1-13
B-988	John Eric Line	USDA - ARS National Programs. Innovative Campylobacter Enumeration Methodologies
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B-997	CDC	Campylobacter Isolates in the United States 1982-1986
B-998		Baytril Poultry Sales vs. % fluoroquinolone Resistant <i>C. jejuni</i>
B-999	Minnesota Dept. of Health	2/15/01 letter to N. Beaver re: raw data from study "quinolone-resistant <i>Campylobacter jejuni</i> infections in Minnesota, 1992-1998" and enclosing most raw data requested
B-1000	Minnesota Dept. of Health	3/19/01 letter to N. Beaver attaching 1998 data
B-1001		Key for chicken data
B-1002		Key for human data, 1996-1997 case-control study
B-1003		Tables - Prevalence of Selected Microorganisms in Broiler Carcass Rinse Fluids, etc.
B-1004	Minnesota Dept. of Health	Antimicrobial Susceptibilities of Selected Pathogens 2000
B-1005	EIP Connecticut -- Emerging Infections Program	CT FoodNet News. What is FoodNet? April 2001
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B-1009	NARMS	2000 NARMS for Enteric Bacteria Participants (Human Isolates) Annual Report
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B-1011	NADA	FOI Summary; NADA 140-828 (supplement); Baytril (enrofloxacin); October 4, 1996 -- Editor's abstract, p. 1-54
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B-1016	Barbara Waters and Julian Davies	Amino Acid Variation in the GyrA Subunit of Bacteria Potentially Associated with Natural Resistance to Fluoroquinolone Antibiotics. Antimicrobial Agents & Chemotherapy, Dec. 1997, Vol. 41, No. 12, pp. 2766-2769
B-1017	J.P. Butzler; M.B. Skirrow	Campylobacter Enteritis. Clinics in Gastroenterology, Sept. 1979, Vol. 8, No. 3, pp. 737-765
B-1018	Stuart B. Levy	Antibiotic Disruption of Microbial Ecology
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B-1020	Louis A. Cox	Risk Analysis Foundations, Models and Methods, Chapter 2, Section 5, pp. 92-131
B-1021	U.S. Congress, Office of Technology Assessment	Impacts of Antibiotic-Resistant Bacteria. Office of Technology Assessment, Congress of the U.S., pp. 1 -183
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B-1024	Thomas R. Beam, Jr.	Fluoroquinolones in Animal Feeds. ASM News, Vol. 60, No. 7 (1994), pp. 348-349
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B-1029	Brisabois A. Martel	Resistance in Zoonotic Salmonella in France.
B-1030	George L. Drusano; David E. Johnson; Mark Rosen; Harold C. Standiford	Pharmacodynamics of a Fluoroquinolone Antimicrobial Agent in a Neutropenic Rat Model of <i>Pseudomonas</i> Sepsis. Antimicrobial Agents and Chemotherapy, Vol. 37, No. 3, Mar. 1993, pp. 483-490
B-1031		Advisory Committees tell FDA-CVM: Restrict fluoroquinolone uses in food-producing animals. JAVMA, Vol. 205, No. 1, July 1, 1994
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B-1033		Antibiotic Resistance. Hearings before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology. U.S. House of Representatives, 98th Congress, 2nd Session, December 18-19, 1984, No. 150
B-1034	John D. Graham, Ph.D.	The Role of Precaution in Risk Assessment and Management: An American's View. Office of Management of Budget, pp. 1-6
B-1035	CDC	10/2/01 FOIA request letter from N. Beaver to FOI Office in Atlanta, GA requesting all Ciprofloxacin susceptibility test results for all Campylobacter isolates from the case control study identified in the following article "Eating Chicken or Turkey Outside the Home Associated with Domestically Acquired Fluoroquinolone-Resistant <i>Campylobacter</i> Infections: A FoodNet Case-Control Study," along with attached e-mail dated 2/26/02 from Katherine Norris at CDC attaching same.
B-1036	Paul V. Effler, M.D.	Memo from Hawaii Dept. of Health to N. Beaver enclosing Campylobacter questionnaires pertaining to the article "Sporadic Campylobacter jejuni Infections in Hawaii: Associations with Prior Antibiotic Use and Commercially Prepared Chicken."
B-1037	CDC	1/7/02 FOIA request letter from N. Beaver to FOI Office in Atlanta, GA requesting all Naladixic Acid susceptibility test results for all C. jejuni isolates from the FoodNet surveillance database for years 1997-2000, along with attached e-mail dated 2/26/02 from Katherine Norris at CDC attaching same
B-1038	CDC	1/7/02 FOIA request letter from N. Beaver to FOI Office in Atlanta, GA requesting "all susceptibility test results for all Salmonella isolates from the FoodNet surveillance database for years 1999-2000, along with attached e-mail dated 2/26/02 from Katherine Norris at CDC attaching same
B-1039	CDC	12/27/00 letter from FOIA to G. Krauss enclosing documents relating FoodNet Campylobacter Case Control Study 1998-1999 from CDC foodborne and diarrhea disease branch
B-1040	CDC	11/20/01 FOIA request letter from N. Beaver to FOI Office in Atlanta, GA requesting "close-out 2000 data" for all Ciprofloxacin susceptibility test results for all C. jejuni isolates from the FoodNet surveillance database for year 2000
B-1041	CDC	E-mail dated 3/4/02 from Lynn Armstrong at CDC enclosing 2000 Campylobacter data and 2000 Salmonella data
B-1042	CDC	Preliminary FoodNet Data on the Incidence of Foodborne Illnesses -- Selected Sites, United States, 2001
B-1043	N.J. Stern; J.E. Line; R.J. Meinersmann	Control of Campylobacter jejuni in Poultry. Poultry Microbiological Safety Research, Athens, GA
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B-1046	Martin J. Blaser; Deborah J. Duncan	Human Serum Antibody Response to Campylobacter jejuni Infection as Measured in an Enzyme-Linked Immunosorbent Assay. Infection and Immunity. American Society for Microbiology. Vol. 44, No. 2, May 1984, p. 292-298
B-1047	Herman Goossens, M.D., Ph.D.	Overview of Campylobacteriosis Treatment Problems, p. 1-9
B-1048	David C. Hooper, M.D.	Review of the Clinical Use of Quinolones in Human Medicine: Western Hemisphere
B-1049	Marc Lipsitch; Carl T. Bergstrom; Bruce R. Levin	The Epidemiology of Antibiotic Resistance in Hospitals: Paradoxes and Prescriptions. Dept. of Biology, Atlanta, GA
B-1050	Irving Nachamkin	Campylobacter jejuni. Foodborne Pathogenic Bacteria, p. 159-170
B-1051	Thomas P. Oscar	The Development of a Risk Assessment Model for Use in the Poultry Industry. USDA, p. 371-381
B-1052	Randall S. Singer; James T. Case; Tim E. Carpenter; Richard L. Walker; Dwight C. Hirsch	Assessment of spatial and temporal clustering of ampicillin- and tetracycline-resistant strains of Pasteurella multocida and P haemolytica isolated from cattle in California. JAVMA, Vol. 212, No. 7, April 1, 1998
B-1053	P. Teufel and K. Sturzonhecker	Virulence tests for Campylobacter. WHO Campylobacter consultation (1994)
B-1054	Therese Brondsted; Tine Hald; Birgitte Beck Jorgensen	Annual Report on Zoonoses in Denmark 1999. Ministry of Food, Agriculture and Fisheries. p. 1-28.
B-1055	Danish Veterinary Laboratory	Campyforum presents Campylobacter Control in Poultry - A Challenge to industry and scientists. Nov. 26, 2000, 1-64
B-1056		2/28/00 e-mail to K. Ewert re: Campylobacter references, new literature citations
B-1057		2/3/00 e-mail to K. Ewert re: revised review of FDA draft document
B-1058		9/5/99 e-mail to K. Ewert re: unexpected event, NEJM article
B-1059	K. Ewert	Presentation to Texas Cattle Feeders Assoc., Board of Directors Meeting, January 2001, p. 1-4
B-1060	K. Ewert	Presentation to Poultry Health and Processing, October 1999, p. 1-12
B-1061	K. Ewert	Presentation to National Broiler Council, November 1998, p. 1-14

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B-1062	D.G. Newell; J.E. Shreeve; M. Toszeghy; G. Domingue; S. Bull; T. Humphrey; G. Mead	Changes in the Carriage of Campylobacter Strains by Poultry Carcasses during Processing in Abattoirs. Applied and Environmental Microbiology, June 2001, Vol. 67, No. 6, p. 2636-2640
B-1063	Marleen Van Looveren; Georges Daube; Lieven De Zutter; Jean-Marie Dumont; Christine Lammens; Monik Wijdooghe; Peter Vandamme; Martine Jouret; Marc Cornelis; Herman Goossens	Antimicrobial susceptibilities of Campylobacter strains isolated from food animals in Belgium. British Society for Antimicrobial Chemotherapy, (2001) 48, 235-240
B-1064		10/27/00 FOIA request letter from G. Krauss to FOI Office in Atlanta, GA requesting all 1999 preliminary FoodNet data regarding Salmonella and Campylobacter isolates to Naladixic Acid and Ciprofloxacin; all data from 1996-1997 FoodNet Population Phone Survey from the CDC Foodborne and Diarrhea Diseases Branch; all data from 1998-1999 FoodNet Population Phone Survey from the CDC Foodborne and Diarrhea Diseases Branch; and all data, from the 1996 FoodNet Physicians Survey from the CDC Foodborne and Diarrhea Diseases Branch, along with response attachments of same
B-1065		1/4/01 FOIA request letter from N. Beaver to K. Smith at the Minnesota Dept. of Health, Acute Disease Epidemiology requesting information under the Data Practices Act, chapter 13 and asking for the raw data contained in the study "Quinolone-Resistance Campylobacter jejuni Infections in Minnesota, 1992-1998," along with response attachments of same
B-1066		10/27/00 FOIA request letter from G. Krauss to FOI Office in Atlanta, GA requesting the procedures and all resulting data relating to "FoodNet Campylobacter Case Control Study 1998-1999" from CDC Foodborne and Diarrhea Disease Branch, along with response attachments of same
B-1067		10/27/00 FOIA request letter from G. Krauss to FOI Office in Atlanta, GA requesting all Ciprofloxacin susceptibility test results for all C. jejuni isolates from the FoodNet surveillance database from 1996 to present; and the protocol for sample collection and susceptibility testing for isolates referenced in request no. 1, above, along with attachments of same
B-1068	Food Chemical News	Fluoroquinolone use scrutinized by WHO report. Food Chemical News, December 15, 1997
B-1069		Infectious Diseases and Etiologic Agents. Part III
B-1070		Summary of Campylobacter data. USDA

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B-1072	Lester Crawford	General Campylobacter comments. From Lester Crawford at VMAC meeting (Jan. 1999). Georgetown Risk Assessment
B-1073		Status of Isolates in Enterococci Pilot Study, October 1998
B-1074	Paula Cray	11/10/98 e-mail from P. Cray to Tom Shryock regarding Campylobacter resistance reply
B-1075		Antibiotic MIC table
B-1076	Smith, et al.	Quinolone-resistant Campylobacter jejuni infections in Minnesota Residents, 1996.
B-1077		Patients infected with Resistant C. jejuni subtypes also isolated from retail chicken products, Minnesota, 1997
B-1078		Summary of Data from Minnesota Dept. of Health
B-1079	Minnesota Dept. of Health	Quinolone-resistant Campylobacter jejuni Infections Associated with Foreign Travel, 1996
B-1080	Minnesota Dept. of Health	1997 Recommended Schedules for Routine Childhood and Adult Immunizations. Minnesota Dept. of Health - Disease Control Newsletter, Vol. 25, No. 2, p. 13-20
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B-1082	Michael Stegemann	4/22/98 letter from Stegemann to Kirk Smith at the Minnesota Dept. of Health re: use of enrofloxacin in Minnesota
B-1083	Michael Stegemann	Memo from Stegemann to Kirk Smith attaching questions re: ICAAC presentation and phone report with CVM concerning the Campylobacter situation in Minnesota
B-1084	K.E. Smith; J.M. Besser; F. Leano; J.B. Bender; J.H. Wicklund; B. Johnson; C.W. Hedberg; K. Vought; K.L. MacDonald; M.T. Osterholm	Fluoroquinolone-resistant Campylobacter isolated from humans and poultry in Minnesota. Abstracts of the 37th Interscience Conference on Antimicrobial Agents and Chemotherapy. September 28 - October 1, 1997
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B-1086	Cecile Lahellec; P. Colin	Relationship Between Serotypes of Salmonellae from Hatcheries and Rearing Farms and Those from Processed Poultry Carcasses. British Poultry Science, 26: 179-186. 1985
B-1087	J.S. Bailey; R.J. Buhr; N.A. Cox; M.E. Berrang	Effect of Hatching Cabinet Sanitation Treatments on Salmonella Cross-Contamination and Hatchability of Broiler Eggs. 1996 Poultry Science 75: 191-196
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B-1091	N.A. Cox; J.S. Bailey; M.E. Berrang	Diminishing Incidence and Level of Salmonellae in Commercial Broiler Hatcheries. 1997 j. Appl. Poultry Res. 6: 90-93
B-1092	P.L. Clarke	6/19/98 letter enclosing Professor G. Mead's paper entitled: "The Safety of Poultry Products: Present Trends and Future Developments," June 1998
B-1093	O.E. Heuer; K. Pedersen; J.S. Andersen; M. Madsen	Prevalence and antimicrobial susceptibility of thermophilic Campylobacter in organic and conventional broiler flocks. Letters in Applied Microbiology 2001, 33, 269-274
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B-1104	Dr. Trudy M. Wassenaar	Comments of Dr. Trudy Wassenaar to NOOH Docket, Docket No. 00N-1571
B-1105	Eva Berndtson, DVM, Ph.D.	Comments of Dr. Eva Berndtson to NOOH Docket, Docket No. 00N-1571
B-1106	Robert A. Norton, Ph.D.	Comments of Dr. Robert A. Norton to NOOH Docket, Docket No. 00N-1571
B-1107	Bruce W. Little, DVM	Comments of Bruce W. Little, DVM to NOOH Docket, Docket No. 00N-1571
B-1108	Louis A. Cox, Jr.	Comments of Louis A. Cox, Jr. to NOOH Docket, Docket No. 00N-1571
B-1109	Eric Gonder, DVM	Comments of Eric Gonder, DVM to NOOH Docket, Docket No. 00N-1571
B-1110	Dr. Jaap A. Waggenaar	Comments of Dr. Jaap A. Waggenaar to NOOH Docket, Docket No. 00N-1571
B-1111	Dennis P. Wages, DVM	Comments of Dennis P. Wages, DVM to NOOH Docket, Docket No. 00N-1571
B-1112	Diane G. Newell, Ph.D.	Comments of Dr. Diane Newell to NOOH Docket, Docket No. 00N-1571
B-1113	Mary Alice Smith, Ph.D.	Comments of Dr. Mary Alice Smith to NOOH Docket, Docket No. 00N-1571
B-1114	James W. Patterson, Ph.D.	Comments of Dr. James W. Patterson to NOOH Docket, Docket No. 00N-1571
B-1115	John R. Glisson, Ph.D.	Comments of Dr. John Glisson to NOOH Docket, Docket No. 00N-1571
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B-1117	Terry N. TerHune, Ph.D.	Comments of Dr. Terry N. TerHune to NOOH Docket, Docket No. 00N-1571
B-1118	Stephen Pretanik - National Chicken Council	Comments of Stephen Pretanik of the National Chicken Council to NOOH Docket, Docket No. 00N-1571
B-1119	Paul Sundberg, Ph.D. (National Pork Producers Council) and Thomas J. Burkgren, DVM (American Assoc. of Swine Veterinarians)	Comments of Paul Sundberg, Ph.D. (National Pork Producers Council) and Thomas J. Burkgren, DVM (American Assoc. of Swine Veterinarians) to NOOH Docket, Docket No. 00N-1571

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B-1132	Noreen V. Harris; Terri Kimball; Noel S. Weiss; Charles Nolan	Dairy Products, Produce and Other Non-Meat Foods as Possible Sources of <i>Campylobacter jejuni</i> and <i>Campylobacter coli</i> Enteritis. <i>Journal of Food Protection</i> , Vol. 49, May 1986, p. 347-351
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B-1139	Qijing	Upcoming paper of Qijing
B-1140		1999-2000 FSIS Baseline Broiler Data (pending publication)
B-1141		Friedman paper on 1998-1999 Case Control Study (pending publication)
B-1142		Kassenborg paper on 1998-1999 Case Control Study (pending publication)
B-1143	Rita Tolcin; Margaret M. LaSalvia; Barbara A. Kirkley; Emily A. Vetter; Franklin R. Cockerill, III; Gary W. Procop	Evaluation of the Alexon-Trend ProSpecT <i>Campylobacter</i> Microplate Assay. <i>Journal of Clinical Microbiology</i> , Oct. 2000, p. 3853 - 3855
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B-1147	CDC	Campylobacter Infections - General Information
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B-1149	US FDA	Infective Dose Information. Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. Bad Bug Book
B-1150	NCC	CDC Confirms Review of Foodborne Illness Estimates. National Broiler Council (NCC) Washington Report. August 14, 1998
B-1151	Qijing	Upcoming paper of Qijing
B-1152		1999-2000 FSIS Baseline Broiler Data (pending publication)
B-1153		Friedman paper on 1998-1999 Case Control Study (pending publication)
B-1154		Kassenborg paper on 1998-1999 Case Control Study (pending publication)
		Bayer reserves the right to rely on all documents on CVM's § 12.85 submission.
		Bayer reserves the right to supplement documents that should have been submitted by CVM, but were not.