

chronologically "new" evidence or can be a new look at evidence in existence at the time the new animal drug application was approved. Bayer's argument that the Administrative Law Judge should add a causation element to the Center's burden is unfounded. CVM is not required to answer the safety questions raised; that burden is on Bayer. Further, CVM maintains that if the risks and benefits of Baytril use in poultry are to be considered, the proper scope of that consideration is whether the benefits to human health from use of this drug in poultry outweigh the risks to human health from use of this drug in poultry, and that costs/economic benefits not be considered. Finally, CVM urges the consideration of the safety of Baytril for use in poultry as opposed to Bayer's suggestion to separate issues for chickens and turkeys.

I. The Issues for Hearing, as Set Out by the Commissioner in the Notice of Hearing, Properly Reflect CVM's Statutory Burden

A. The Commissioner has Set Out the Issues for Hearing

The Commissioner set out the issues for hearing which he believes are appropriate to reach an ultimate decision on the safety of Baytril use in poultry. Although the Administrative Law Judge has the discretion to modify the issues (see 21 CFR 12.35), CVM urges the Administrative Law Judge not to modify the Commissioner's issues without compelling reasons. CVM contends that Bayer has not provided any compelling reasons to modify the issues as set out in the Notice of Hearing.

B. CVM Has the Burden to Present Evidence from which Serious Questions About the Safety of Baytril Use in Poultry May be Inferred

The issues as Bayer proposes to reformulate them would impose additional burdens on the Center in excess of those set out in the statute, the case law and/or regulations. The Center has the burden to present evidence from which serious questions about the

safety of Baytril use in poultry may be inferred. This is the standard set out in the Administrative Law Judge's initial decision in the Diethylstilbestrol (DES) new animal drug approval withdrawal hearing (Initial Decision at 8), and adopted by the Commissioner in his decision:

"It is, of course, not possible to write a formula, semantic or otherwise, that will tell the decisionmaker exactly how much evidence is required to show that a drug is no longer shown to be safe. The Administrative Law Judge's formulation is as good as any: "In other words, the Bureaus must provide a reasonable basis from which serious questions about the ultimate safety of DES and the residues that may result from its use may be inferred" (I.D. at 8). I adopt this statement of the burden of proof in this proceeding..." 44 Fed. Reg. 54861.

In its Motion to Reformulate Issues for Hearing, Bayer argues that "The statute plainly requires FDA 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". (Bayer Motion at 6.) However, CVM's burden is only to present enough evidence to raise serious question about Baytril's use in poultry. The Commissioner of FDA has spoken explicitly about this issue. In the DES decision, the Commissioner said,

"The manufacturing parties argue that the Bureaus' burden is, in effect, to show that use of the drug is unsafe. There is, however, a clear congressionally recognized difference between "unsafe" and "not shown to be safe." Indeed, the statute uses both terms and clearly distinguished between them. Compare 21 U.S.C. 360b(e)(1)(A) with 21 U.S. C. 360b(e)(1)(B). The former paragraph requires a finding that a drug is "unsafe"; the latter, a finding that the drug is "not shown to be safe." If the two terms were the same, there would not be two subparagraphs.

The Court of Appeals in *Hess & Clark, Division of Rhodia, Inc. v. FDA*, supra, 465 F. 2d at 993, focusing on the residue issue... stated its view of the burden question: We think it implicit in the statute that when the FDA proposes to withdraw an approval because new evidence shows the drug leaves residues, it has an initial burden of coming forward with some evidence of the relationship between the residue and safety to warrant shifting to the manufacturer the burden of showing safety..." 44 Fed. Reg. 54852 at 54861

Case law supports the Center's position. See Hess & Clark, 465 F. 2d at 993. ("the FDA must show... (1) whether the detected residues are related to the use of DES

implants; (2) if so, whether the residues, because of their composition, and in the amounts present in the tissue, present some potential hazard to the public health.") Applying the decision in Hess & Clark to this hearing, CVM need only present enough information that: (1) fluoroquinolone-resistant *Campylobacter* in poultry is related to the use of fluoroquinolones in poultry (e.g., selection pressure and transmission of fluoroquinolone-resistant *Campylobacter* to humans), and (2) the fluoroquinolone-resistant *Campylobacter* present some potential hazard to the public health (e.g., infectious dose, longer duration of illness).

C. The Issues for Hearing as Set Out in the NOH Adequately Reflect the Proper Statutory Standards and Required Burdens

1. Subissue A(1)

Bayer proposes to rephrase subissue A(1) which currently reads as follows:

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

Bayer's proposed reformulation would have the subissue read:

"Whether CVM has presented new evidence that the use of enrofloxacin in chickens causes significant fluoroquinolone-resistant *Campylobacter* spp. in chicken meat consumed by humans?"

The Center opposes this requested modification to subissue A(1) for several reasons. First, Bayer contends that CVM can only rely on wholly new information from that available at the time new drug application for use in poultry was approved. Bayer is wrong; evidence can include a new look at information that the Agency had prior to the approval of a new animal drug application. The plain language of Section 360b(e)(1)(B) supports this reading.

"(B) that new evidence not contained in such application or not available to the Secretary 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 the Secretary 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..." [Emphasis added.] 21 U.S.C. 360b(e)(1)(B)

This language not only allows, but actually requires FDA to look anew at the evidence it had when the application was approved together with subsequently available evidence. Obviously, when the Agency conducts this evaluation, the meaning of evidence that was available when the drug was approved can take on new importance, both when the subsequent evidence changes an initial evaluation/interpretation of data or serves to confirm what the existing evidence shows.

The case law is in complete accord with this interpretation. For example, when some data exist at the time the drug is approved, and additional data confirming that original data or casting a new importance on that data is generated, the Center must re-evaluate the import of existing data. Bell v. Goddard, 366 F 2d 177 (7th Cir. 1966), concerned the appeal from an Agency order withdrawing approval of a new animal drug application under Section 505(e)(2) of the Act, 21 U.S.C. §355(e)(2).¹ This section provides that the Commissioner could withdraw a drug if "clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective" showed the drug was unsafe. (See Bell v. Goddard, *supra* at 181.) In Bell v. Goddard, the Seventh Circuit Court of Appeals held that the approval of a drug can be withdrawn on the basis of a new application of existing information.

In this case an extensive re-evaluation which drew together clinical experience in a manner not previously attempted and which perhaps brought its full impact to the attention of the experts for the first time, provided the basis for the

¹ Section 505(e) applied to new animal drugs prior to the enactment of current Section 512(e).

Commissioner's findings. An interpretation of the statute prohibiting such a new application of existing information would do violence to the paramount interest in protecting the public from unsafe drugs. Bell v. Goddard, at 181.

Although this opinion was interpreting Section 505(e)(2), there is no reason to interpret the Court's ruling as limited to only "clinical experience".

This is supported by agency adjudications as well. The Commissioner's decision in the DES withdrawal hearing, 44 Fed. Reg. 54852, at 54861, states: "...approval may be withdrawn pursuant to the "safety clause" if new evidence, evaluated together with previously existing evidence, shows the drug is not shown to be safe." [Emphasis added.] This decision supports CVM's view that the Center is required to look at new evidence and evaluate it together with existing evidence.

The Commissioner's decision in the Nitrofurans hearing, 56 Fed. Reg. 41902, likewise supports this view. That decision states: "Under both the Delaney and the general safety clauses, approval may be withdrawn if "new evidence", evaluated together with previously existing evidence, shows that the drug is not shown to be safe. [Emphasis added.] Commissioner's Nitrofurans Decision, at 41903.

Although, there was no issue about the newness of information in these administrative hearings, under a plain reading of the statute, and consistent with case law, the Commissioner would be justified in reviewing any new evidence in concert with a re-evaluation of all existing data.

Therefore Bayer's contention that CVM can only rely on evidence available after the drug's approval to raise serious questions of the safety of Baytril use in poultry is wrong. Bayer's Motion to insert the phrase "whether CVM has presented new evidence"

in each of the subissues is contrary to the plain language of the statute, case law and agency administrative adjudications, and should be rejected.

Second, the Center reiterates its opposition to Bayer's attempt to re-characterize the parties' burdens (see argument in Section B above). CVM's burden does not include "causation".

Inserting the word "causes" in the subissue² would serve to require the Center not only to present evidence that raises serious questions of safety, as the courts have held, but would improperly impose on the Center Bayer's burden to answer those questions. If the Center properly raises serious safety questions, and Bayer, the sponsor of Baytril, does not demonstrate the safety thereof, then Baytril will not have been shown to be safe, and must be withdrawn. Any contrary allocation of the burden would invert the statutory requirement that the drug's proponent has the burden of proving its safety, as well as the regulations in 21 C.F.R. §12.87(d), which state,

At a hearing involving issuing, amending, or revoking a ... order relating to the safety or effectiveness of a drug ...the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on that participant in an amendment or revocation proceeding. [Emphasis added.]

Third, Bayer's suggested reformulation attempts to impose a burden not justified in the Act or case law to show that the use of fluoroquinolones in poultry causes "significant" fluoroquinolone-resistant campylobacter in poultry.³ As indicated earlier, Hess & Clark requires CVM to merely present evidence that the problem (there, a residue; here, fluoroquinolone-resistant Campylobacter) is related to the use of the drug

² " Whether CVM has presented new evidence that the use of enrofloxacin in [poultry] causes significant fluoroquinolone-resistant [C]ampylobacter spp. in chicken meat consumed by humans?"

and that these resistant bacteria present a potential threat to public health. Hess & Clark, 465 F.2d at 192.

Bayer states (Motion at 8), "FDA implicitly acknowledges the relevance of the issue of the extent or significance of selection pressure. In the NOH the agency states, CVM has concluded... that the use of fluoroquinolones in poultry is a significant cause of fluoroquinolone-resistant *Campylobacter* on poultry carcasses...' 67 Fed. Reg. 7700. FDA cannot meet its burden of proof without evidence to support this conclusion."

Bayer's argument mistakenly attempts to convert the Center's beliefs into its burden. Regardless of what CVM believes (i.e., that the use of fluoroquinolones in poultry is a significant cause of fluoroquinolone-resistant *Campylobacter* on poultry carcasses), the issue is what the Center is required to show to meet its burden. As indicated above, CVM must only present evidence from which serious questions about the safety of Baytril use in poultry may be inferred.

Fourth, CVM opposes Bayer's proposal to make where the *Campylobacter* is found an issue.⁴ Bayer's addition of the words "in [poultry] meat consumed by humans" would improperly restrict introduction of evidence. CVM's contention is, and its evidence will demonstrate, that the *Campylobacter* is colonized in the poultry's intestines; that it spreads to other birds through the fecal-oral route at poultry growing operations and during transport to slaughterhouses; and, that it contaminates the skin and outside of the carcass and other carcasses during the slaughter, post-slaughter, cooling, and packing processes, and during subsequent holding for sale of the poultry. Although ground poultry meat, as well as the skin and surface of poultry meat, is often contaminated with *Campylobacter*, the muscle itself could be, in many cases, uncontaminated with

³ "Whether CVM has presented new evidence that the use of enrofloxacin in [poultry] causes **significant** fluoroquinolone-resistant [*C*]ampylobacter spp. in [poultry] meat consumed by humans?"

Campylobacter organisms. CVM intends to introduce evidence that this colonization/contamination cycle would be the same when the Campylobacter is fluoroquinolone-resistant or fluoroquinolone-susceptible.

The addition of the phrase "in meat consumed by humans" in subissue A(1) would limit the proper introduction of probative evidence as to carcass rinse data, fecal swab data, data from ceca samples, and the like. Further, if reformulated as Bayer urges, this issue would completely ignore the very important issue of cross contamination of other food with fluoroquinolone-resistant Campylobacter from poultry sources. If Bayer's suggested limiting language is adopted, the parties would be severely limited in the kind of data they could present at hearing, and the Administrative Law Judge and the Commissioner would have an incomplete record on which to base a decision in this matter.⁵

2. Subissue A(2)

Bayer proposes to rephrase subissue A (2) which currently reads as follows:

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

Bayer's proposed reformulation would have the issue read:

"Whether CVM has presented new evidence that fluoroquinolone-resistant Campylobacter spp. in [poultry] caused by the use of enrofloxacin in [poultry] are transferred to humans and are a significant cause of fluoroquinolone-resistant Campylobacter infections in humans?"

⁴ "Whether CVM has presented new evidence that the use of enrofloxacin in [poultry] causes significant fluoroquinolone-resistant [C]ampylobacter spp. **in [poultry] meat consumed by humans?**"

⁵ The Center also notes that Bayer's unsupported factual allegations by counsel of "facts" not yet accepted into evidence (see pages 9-12, 14-15, and 20-21) is inappropriate. Both parties will present evidence through witnesses and documents at the hearing and the Administrative Law Judge will have the opportunity to review that evidence in context of the testimony. CVM will attempt to present its evidence through its witnesses and documents and respectfully requests that the Administrative Law Judge direct Bayer to refrain from counsel testimony in its filings.

This Bayer-requested change would also serve to shift the burden of proof with respect to safety to CVM contrary to the Act. First, by inserting the phrase "caused by the use of"⁶, Bayer seeks to tack a causation element onto this issue (see argument above). Adopting Bayer's proposed changes might require CVM to present evidence that shows that "X" Chicken (or Turkey) was treated with Baytril, that the specific bird became colonized with fluoroquinolone-resistant Campylobacter as a result of the exposure to the drug, that the specific bird was eaten by "Y" Human, that "Y" Human got a fluoroquinolone-resistant Campylobacter infection, and that "Y" Human's fluoroquinolone-resistant Campylobacter infection was traced back to "X" Chicken (or Turkey). This is a far more extensive burden than required by the Act and applicable case law. Whether or not such a burden might be justified in a consumer tort case against Bayer for injury caused to that consumer from the use of Baytril, it is inappropriate under the framework of the Act. Further, Bayer's request for the second change to subissue A(2), inserting "and are a significant cause of" fluoroquinolone-resistant Campylobacter infections in humans",⁷ is inappropriate for the same reasons set out above.

3. Subissue (A)(3)

Bayer proposes to rephrase subissue A(3), which currently reads as follows:

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

⁶ "Whether CVM has presented new evidence that fluoroquinolone-resistant Campylobacter spp. in [poultry] **caused by the use of** enrofloxacin in [poultry] are transferred to humans and are a significant cause of fluoroquinolone-resistant Campylobacter infections in humans?"

⁷ "Whether CVM has presented new evidence that fluoroquinolone-resistant Campylobacter spp. in [poultry] caused by the use of enrofloxacin in [poultry] are transferred to humans **and are a significant cause of** fluoroquinolone-resistant Campylobacter infections in humans?"

Bayer's proposed reformulation would have the issue read:

"Whether CVM has presented new evidence that fluoroquinolone-resistant *Campylobacter* infections in humans caused by the use of enrofloxacin in [poultry] pose a greater potential hazard to public health than was anticipated when the drug was approved?"

Bayer bases its proposal on a rehashing of its argument that CVM must rely on post-approval evidence to show that there is some actual hazard occurring that CVM did not anticipate, or some potential hazard of which CVM was unaware, at the time the drug was approved. Again, Bayer's reliance on the "new" evidence theory is misplaced and CVM reiterates its opposition to this language. CVM submits that if it limited its evaluation of the current safety of Baytril use in poultry to information available only after the drug was approved, it would be remiss in carrying out its responsibilities under the FDCA. Further, for the same reasons explained above, CVM reiterates its opposition to Bayer's attempt to insert a "causation" element in CVM's burden of proof. Moreover, CVM has no legal obligation to present evidence that fluoroquinolone-resistant *Campylobacter* infections in humans caused by the use of Baytril in poultry pose a greater potential hazard to public health than was anticipated at the time the drug was approved. It merely needs to present evidence on the potential adverse effects on human health from the continued use of the drug in poultry.

II. Risk/Benefit Analysis

Bayer has suggested amending the issue of:

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

and replacing it with an issue concerning the risks and benefits of the use of enrofloxacin, including those under some alternative pattern of restricted use:

"Whether the benefits of continued enrofloxacin use in [poultry] under the current recommended or suggested conditions of use in the labeling or under some alternative pattern of restricted use outweigh the risks/costs of such continued use, such that enrofloxacin is safe. This analysis will include consideration of impacts on (a) human health, (b) animal health, (c) the environment, and (d) the economy").

Although the Center objects to Bayer's phrasing of this issue, it is not generally adverse to a limited consideration of the risks and benefits of the drug. It is important, however, to be clear as to what is being considered in that risk/benefit analysis. Case law clearly indicates that the agency's evaluation of the safety of a drug compares the risk to the user of the drug to the therapeutic benefit to that same user of the drug. There is no obligation upon the Center to subject the public to risk for the animal's benefit.⁸

Therefore, any risk/benefit analysis must analyze the risk and benefit from the same viewpoint. Because the safety concern in this hearing is human food safety and human health impact, the proper risk/benefit analysis would need to consider whether the benefits to human health from use of the drug in poultry are proven to outweigh the risk to human health from the use of this drug in poultry.

Moreover, CVM believes that without explicit statutory authorization, economic costs may not be considered in determining the safety of a drug. This includes both the

⁸ See FDA v. Brown and Williamson Tobacco Corporation, 529 US 120 2000, "A fundamental precept of the FDCA is that any product regulated by the FDA – but not banned – must be safe for its intended use. Various provisions of the Act make clear that this refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA. That is, the FDA must determine that there is a reasonable assurance that the product's therapeutic benefits outweigh the risk of harm to the consumer" at 142. See also, US. v. Rutherford, 442 US 544, 1979, "Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit" at 555-556.

costs associated with lost revenue from poultry producers, drug manufacturers, and consumers, as well as environmental costs and other socio-economic costs. Bayer relies on Rhone-Poulenc, Hess & Clark Division v. FDA, 636 F.2d 750 (D.C. Cir. 1980) for the proposition that economic benefit is a proper consideration in a withdrawal action of a veterinary drug on safety grounds. The Rhone-Poulenc Court stated (at 754),

In Hess & Clark v. FDA we held that [t]he typical issue for FDA is not the absolute safety of a drug. Most drugs are unsafe in some degree. Rather, the issue for FDA is whether to allow sale of the drug, usually under specific restrictions. Resolution of this issue inevitably means calculating whether the benefits which the drug produces outweighs the costs of its restricted use. 161 US APP DC @ 413-14, 495 F.2d @ 993-94. (Footnotes omitted). In his decision the Commissioner characterized this language as dictum and expressed the opinion that the statute does not allow him to consider the overall benefits of DES, however, and found that the manufacturers had not proved that these benefits outweigh the risks associated with DES. The Commissioner's arguments regarding the propriety of risk-benefit analysis are repeated in the agency's brief. We decline the invitation to overrule our prior holding, however. The language quoted above was not dictum. Rather, it expressly set forth one of the issues to be considered at the hearing. Whatever the merits of the Commissioner's arguments on the point may be, we are bound by the holding of the Hess & Clark court until we are instructed otherwise by the Supreme Court or an en banc decision of this Court.

The Supreme Court has since effectively "instructed otherwise" in both American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490 (1981) and Whitman v. American Trucking Association, 531 U.S. 457 (2001). American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490 (1981), involved a challenge to the cotton dust standard promulgated by the Occupational Safety and Health Administration (OSHA) under Section 6(b) of the Occupational Safety and Health Act of 1970, 29 U.S.C. §655(b). That section provided that the Secretary must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health..." The Petitioners' argued that the

term "feasible" in the Act included a requirement to conduct a cost/benefit analysis. The Supreme Court rejected this position, holding that, "When Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such intent on the face of the statute." American Textile at 509. Here, even when Congress spoke to a standard that was feasible (in every respect, including technologically and economically), the Court refused to interpret that provision as requiring OSHA to weigh the costs of the standard versus the benefits accrued by the standard.

Only last year, in Whitman v. American Trucking Association, 531 U.S. 457 (2001), the Supreme Court held that the Clean Air Act bars EPA from considering implementation costs when setting appropriate National Ambient Air Quality Standards (NAAQS) at a level to protect public health. The Court held that consideration of implementation costs

is *both* so indirectly related to public health *and* so full of potential for canceling the conclusions drawn from direct health effects that it would have been expressly mentioned in §§108 and 109 had Congress meant it to be considered. Yet while those provisions describe in detail how the health effects of pollutants in the ambient air are to be calculated and given effect, See §108(a)(2), they say not a word about costs. Whitman v. ATA, at 469. [Emphasis in the original.]

This holding applies equally to a drug safety determination under the FDCA since consideration of costs in the drug safety determination is both so indirectly related to public health and so full of the potential to cancel the conclusions drawn from public health benefits. The FDCA does not on its face require a consideration of costs (or economic benefits) in evaluating the safety of a drug. Under American Textile and Whitman v. ATA, it would be impermissible to consider such costs.

With respect to Bayer's insertion of the phrase "under the current recommended or suggested conditions of use in the labeling or under some alternative pattern of restricted

use",⁹ the extra-label use prohibition that specifically prohibits the use of Baytril for non-label purposes currently bars any other "alternative pattern of restricted use" (See 62 FR 27944 (1997)).

Bayer elected to request a formal hearing on whether Baytril is safe under its approved labeled conditions of use. Bayer did not avail itself of the regulatory opportunity to file a supplemental new animal drug application requesting approval of Baytril under other conditions of use. Therefore, Bayer should not be heard to suggest, as a hearing issue, alternatives that Bayer never put before the Center in the manner provided for in the FDCA and FDA's regulations.

While CVM is not generally adverse to a limited consideration of human health risks and benefits, it does not believe that subissue A (3) needs to be modified in order to permit this consideration. Bayer is already free to proffer documentation of any health benefits to humans (excluding economic benefits/costs) under existing subissue A(3).¹⁰ The Administrative Law Judge, and ultimately the Commissioner, can weigh these benefits against the health risks to humans from the use of the drug in poultry, presented by CVM.

III. Issues Regarding the Safety of Baytril Use in Chickens and Turkeys Should be Heard Together

For reasons of judicial efficiency, and simplicity, the issues of whether the drug is safe for use in chickens and in turkeys should be presented and decided together. Further, there is no jury here to confuse. The Center will present its evidence, and Bayer will

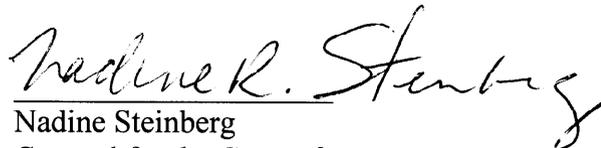
⁹ ("Whether the benefits of continued enrofloxacin use in [poultry] **under the current recommended or suggested conditions of use in the labeling or under some alternative pattern of restricted use** outweigh the risks/costs of such continued use, such that enrofloxacin is safe. ...")

present its evidence. The Administrative Law Judge will be able to determine at that time whether to rule on the safety of Baytril in poultry or to rule separately regarding the individual species at that time. In the DES hearing, there were similar concerns about the safety of DES used in different species. The Administrative Law Judge, the Commissioner, and the Court of Appeals were able to discern the necessity of withdrawing the approval for more than one species, even though the existing evidence concentrated on one species. See, Commissioner's DES decision, 44 Fed. Reg. 54864, 1979; Rhone-Poulenc, supra at 753.

Conclusion

CVM believes that the issues set out by the Commissioner in the Notice of Hearing (NOH) accurately reflect the parties' respective burdens and the standards governing the hearing, and the Center urges the Administrative Law Judge to deny Bayer's Motion to Reformulate Issues for Hearing. A proposed Order accompanies this Response.

Submitted on this 22nd day of April, 2002 by:



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¹⁰ Existing subissue A(3) states: "Whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe?"

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

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In the Matter of:)

FDA DOCKET: 00N-1571
DATE: April 22, 2002

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

Having considered Bayer Corporation's Motion to Reformulate Issues for Hearing and the Center for Veterinary Medicine's Response in Opposition thereto, Bayer's Motion is hereby DENIED.

The issues for Hearing remain as set out in the Notice of Hearing, 67 Fed. Reg. 7700, February 20, 2002. The Parties are DIRECTED that economic costs are not an issue in this Hearing and testimony and/or documents regarding economic costs or benefits will not be admitted into evidence.

Dated this the ____ day of ____, 2002.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Rm. 9-57, HF-3
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Enrofloxacin Hearing
Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Response to Bayer's Motion to Reformulate Issues for Hearing was hand delivered this 22nd day of April, 2002, to:

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

The Office of the Administrative Law Judge
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I also certify that the foregoing Response was e-mailed and also mailed, postage prepaid, this 22nd day of April, 2002, to:

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I also certify that the foregoing Response was e-mailed, this 22nd day of April, 2002, to:

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I also certify that the foregoing Response was mailed, postage prepaid, this 22nd day of April, 2002, to:

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