



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
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MEMORANDUM

Date: November 9, 2001
To: Commenters to Docket No. 00N-1571 (Enrofloxacin for Poultry)¹
From: Counsel for the Commissioner,
Office of the Chief Counsel

Enclosed please find copies of correspondence involving Docket No. 00N-1571 which were filed with FDA's Dockets Management Branch on November 2, 2001, pursuant to 21 CFR 10.55(d).

cc: Docket 00N-1571, Dockets Management Branch, FDA (with list of commenters attached)

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¹ A search of Docket No. 00N-1571 was performed to identify all commenters. This mailing is being sent to commenters whose comment included a legible, complete return address.

00N-1571

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Office of the Chief Counsel
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October 22, 2001

Kent D. McClure, D.V.M., J.D.
General Counsel
Animal Health Institute
1325 G St., N.W., Suite 700
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Dear Dr. McClure:

I write in response to your September 28, 2001, letter requesting a meeting to discuss the legal standard used under the Federal Food, Drug, and Cosmetic Act to determine the safety of new animal drugs. The draft citizen petition attached to your letter, which sets out your views on the legal standard, requests withdrawal of the Notice of Opportunity for Hearing for enrofloxacin that FDA's Center for Veterinary Medicine published in the Federal Register on October 31, 2001.

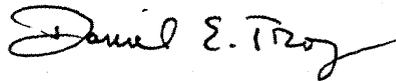
I am advising the Office of the Commissioner in the proceeding to withdraw approval of enrofloxacin. Under FDA's regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between FDA officials advising the Office of the Commissioner and persons outside FDA. See 21 C.F.R. 10.55(d)(1). Thus, I am unable to meet with you about the issues you raise in your September 28 correspondence. In addition, under these regulations, a copy of this correspondence and my response must be placed in the FDA docket and served on other participants. 21 C.F.R. 10.55(d)(3).

I recognize this situation, and my inability to meet with you, may be frustrating. However, any meeting would likely affect my ability to participate in the withdrawal proceeding, which would not serve anyone's interests.

Kent D. McClure, D.V.M., J.D.
Page 2

I look forward to hearing from you and working with you on other issues of interest to you and AHI.

Sincerely,

A handwritten signature in cursive script that reads "Daniel E. Troy". The signature is written in dark ink and is positioned above the typed name.

Daniel E. Troy
Chief Counsel

cc: Cheryl V. Reicin, Esq.

Kent D. McClure, DVM, JD
General Counsel

September 28, 2001

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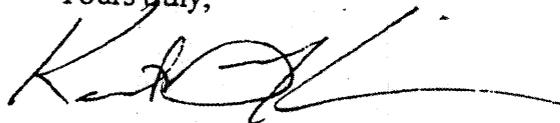
Dear Mr. Troy:

The ANIMAL HEALTH INSTITUTE (AHI) is a national trade association representing manufacturers of animal health products – pharmaceuticals, biologicals and feed additives used in modern food production and the medicines that keep pets and livestock healthy. Our member companies produce the vast majority of all such products in the United States, as well as the world market.

Attached is an analysis of the “reasonable certainty no harm” standard that has been the subject of much discussion within our industry. We would appreciate the opportunity to meet with you to discuss this issue of vital importance to the animal health products industry. We have previously attempted to engage FDA counsel on this issue, but have not been able to do so. We have made these points in several comments and have even met with senior CVM officials and counsel, who simply refused to discuss the issue.

We look forward to meeting with you at your earliest convenience and will follow up with your office.

Yours truly,



Kent D. McClure, DVM, JD

Kent D. McClure, DVM, JD
General Counsel

August 31, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
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Rockville, Maryland 20857

DRAFT

CITIZEN PETITION

The ANIMAL HEALTH INSTITUTE (AHI) submits this petition under sections 201, 512 and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 360b, 371) to request the Commissioner of Food and Drugs to refrain from use of the "reasonable certainty of no harm" standard for determining whether a new animal drug is "safe" within the meaning of the Food, Drug and Cosmetic Act. AHI is the national trade association representing manufacturers of animal health products - pharmaceuticals, biologicals and feed additives used in modern food production and the medicines that keep pets healthy. As such, AHI certainly supports the marketing of safe and effective new animal drugs. Indeed, AHI members annually spend hundreds of millions of dollars in research designed to demonstrate the safety and efficacy of animal health products. However, the "reasonable certainty of no harm standard," as applied by the FDA Center for Veterinary Medicine, is inappropriate.

Additionally, AHI requests that the FDA consider the interaction between the Food Drug and Cosmetic Act and the Meat Inspection Act and the Poultry Products Inspection Act when developing policy for the review of antimicrobial new animal drugs.

AHI has repeatedly pointed out in comments and at workshops that the Center for Veterinary Medicine has spent little time publicly discussing the legal underpinnings to the various policy initiatives underway and sought more open public analysis. We have even met with FDA counsel and senior management who refused to discuss the issue. Therefore, we file this petition.

A. ACTION REQUESTED

1. AHI requests that the Center for Veterinary Medicine immediately cease use of the "reasonable certainty of no harm" standard in the determination of whether a new animal drug is "safe" within the meaning of the Food, Drug and Cosmetic Act and utilize a risk / benefit analysis as directed by applicable case law.

2. AHI requests that the Center for Veterinary Medicine consider the interaction between the Food Drug and Cosmetic Act and the Meat Inspection Act and the Poultry Products Inspection Act when developing policy for the review of antimicrobial new animal drugs.

B. STATEMENT OF GROUNDS

1. "REASONABLE CERTAINTY OF NO HARM"

The Center for Veterinary Medicine (CVM) has recently indicated in several documents and workshops that it is using a standard it refers to as "reasonable certainty of no harm" to determine whether a new animal drug is "safe" within the meaning of the Food, Drug and Cosmetic Act. For example, in the document *An Approach for Establishing Thresholds in Association with the Use of Antimicrobial Drugs in Food-Producing Animals: A Discussion Document*, <http://www.fda.gov/cvm/antimicrobial/threshold21.pdf> at page 3 line 99 to 102 ("Threshold Document"), CVM states "As required by the Federal Food, Drug, and Cosmetic Act (FFDCA), CVM has applied the reasonable certainty of no harm standard to human safety considerations associated with the use of antimicrobial drugs in food-producing animals." The assertion by CVM that the "reasonable certainty of no harm" standard is required by the Food Drug and Cosmetic Act is without merit and contrary to controlling case law. It is merely a restatement of a CVM position that was overruled by the United States Court of Appeals for the D.C. Circuit more than twenty years ago.

A. THE STANDARD FOR "SAFE" IN THE CONTEXT OF ANIMAL DRUGS

Safe is defined in the Food, Drug and Cosmetic Act as "referring to the health of man or animal." 21 USC § 321(u). Additional guidance with respect to the determination of "safe" for new animal drugs is offered with a non-exclusive listing of factors to be considered. 21 USC § 360b(d)(2). As explained further below, interpretative case law has held that inherent in the weighing of these statutory factors is a risk / benefit analysis. Indeed, such is implicit by the use of such statutory factors as "probable consumption," "cumulative effect," "safety factors," and whether the conditions of use are reasonably certain to be followed in practice. To the contrary, CVM utilizes a standard that does not utilize a risk / benefit analysis.

CVM has not established a statutory or regulatory basis for this standard. In the Threshold Document, CVM asserts that the Food, Drug and Cosmetic Act requires the use of the "reasonable certainty of no harm" standard. Interestingly, in the Notice of Opportunity for Hearing on veterinary fluoroquinolones used in chickens and turkeys (NOOH) published by CVM, they do not take the same position. In the NOOH, CVM merely contends that "safe" can be defined as "reasonable certainty of no harm." Notice of Opportunity for Hearing, 65 Fed. Reg. 64, 956 (2000). CVM has entirely failed to explain its legal analysis of the Food, Drug and Cosmetic Act, controlling case law, or the Food, Drug and Cosmetic Act's interaction with the Meat Inspection Act and the Poultry Products Inspection Act.

CVM's rationale for use of the "reasonable certainty of no harm" standard appears to be that this is the definition for food additives found in the Code of Federal Regulations, and that since animal drugs were regulated as food additives prior to 1968, it applies to them as well. Particularly since the 1968 amendments only consolidated FDA's statutory authority. Notice of Opportunity for Hearing, 65 Fed. Reg. 64, 956 (2000). However, there are several problems with such an analysis.

First, the regulations promulgated by FDA under the food additive amendments have over time articulated different definitions of safe. The one currently in place was not promulgated until the late 1970s. 21 CFR § 170.3(i). The food additive provisions of the FFDCA have not applied to animal drugs since 1968 with the animal drug amendments. 21 U.S.C. §321(s)(5). So, the current food additive rule (which on its face applies only to food additives) has never applied to animal drugs.

Second, in the DES withdrawal proceedings, when a manufacturer relied upon FDA food additive language, CVM argued that the food additive provisions of the FFDCA and the food additive regulations were not applicable or binding to new animal drugs. 44 Fed.Reg. 54882-3 (1979). CVM appears to be highly inconsistent on this issue, arguing that the food additive provisions apply or don't apply to new animal drugs according to their immediate need.

Third, the FFDCA itself does not provide the standard (other than the implicit direction of a risk / benefit analysis) for the determination of safety, and CVM has not promulgated any rules setting the standard in the context of animal drugs. Courts that have attempted to determine the standard against which the CVM must evaluate safety data for a new animal drugs have determined that no particular standard is mandated by the FFDCA. "The Food, Drug, and Cosmetic Act does not indicate the standard an applicant must meet to demonstrate a new drug's safety or the evidence upon which the FDA must base its safety determination." *Stauber v. Shalala*, 895 F.Supp. 1178, 1191 (W.D. Wis 1995)(emphasis added); *American Cyanamid Co. v. FDA*, 606 F.2d 1307, 1313-1314 (D.C. Cir. 1979)(The FFDCA contains no provision delineating the nature of the evidentiary showing required to prove the safety of a new drug).

B. AS APPLIED, CVM IS PRECLUDED FROM USE OF THE "REASONABLE CERTAINTY OF NO HARM" STANDARD FOR THE DETERMINATION OF "SAFE" IN THE CONTEXT OF NEW ANIMAL DRUGS

i. CVM FAILS TO PERFORM A RISK - BENEFIT ANALYSIS

Current application of the "reasonable certainty of no harm" standard by CVM is such that a risk / benefit analysis is not performed. Rather, if risk or potential risk is identified, the position is that the standard cannot be met. At a CVM workshop on antimicrobial resistance, Dr. Alan Rulis, an FDA official, explained that a risk - benefit analysis is specifically not performed under the "reasonable certainty of no harm" standard. Draft Risk Assessment and the Establishment of Resistance Thresholds Workshop, December 10, 1999 Transcript at 16, Line

12. (“[Reasonable certainty of no harm] does not weigh risks and benefits.”)
<http://www.fda.gov/cvm/antimicrobial/v121099.pdf>.

ii. CVM IS REQUIRED TO PERFORM A RISK - BENEFIT ANALYSIS

In this context, CVM is precluded from utilizing the “reasonable certainty of no harm” standard because CVM applies it in a manner contrary to controlling law, which requires CVM to conduct a risk - benefit analysis when determining the safety of new animal drugs. This is implicit in the FFDCA by the use of such statutory factors as “probable consumption,” “cumulative effect,” “safety factors,” and whether the conditions of use are reasonably certain to be followed in practice. Additionally, the U.S. Court of Appeals for the District of Columbia Circuit has at least twice held that CVM must consider the benefits of new animal drugs in the context of the determination of “safe” of a new animal drug under the FFDCA. *Hess & Clark v. FDA*, 495 F.2d 975 (D.C. Circuit 1974); *Rhone-Poulenc v. FDA*, 636 F.2d 750 (D.C. Circuit 1980).

In *Hess & Clark*, the Court reviewed CVM’s determination of the safety of an animal drug used in a food producing species and specifically held that a risk/benefit analysis was inherent in the approval process for new animal drugs. 495 F.2d at 993, 994. “[T]he issue for the 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 outweigh the costs of its restricted use.” *Id.* (emphasis added). The *Hess & Clark* case was remanded to the agency for further agency action.

The agency conducted an administrative hearing and published its findings in the Federal Register. A portion of the Federal Register publication addressed the issue of a risk / benefit analysis for animal drugs and the *Hess & Clark* decision. 44 Fed. Reg. 54,852, 54,881-83 (1979). The FDA Commissioner stated that the language in the *Hess & Clark* decision indicating that the agency must consider the benefits of use of an animal drug was dictum, not binding on the agency. *Id.* The Commissioner then pointed to (1) the legislative history behind the animal drug amendments of 1968, (2) a failure of the *Hess & Clark* court to understand the differences in human and animal drugs, (3) the legislative history behind the FFDCA food additive provisions, (4) the CVM position against consideration of the benefits of an animal drug, and (5) “policy arguments” to conclude that the FFDCA does not allow the agency to consider the benefits of a new animal drug when determining safety. *Id.*

The same case again came before the US Court of Appeals for the D.C. Circuit in *Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750 (D.C. Cir. 1980). The court addressed whether its risk / benefit language in *Hess & Clark* was binding on the agency. The court stated:

In *Hess & Clark v. FDA* we held that

[T]he typical issue for the FDA is not the absolute safety of a drug. Most drugs are unsafe in some

degree. Rather, the issue for the 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 outweigh the costs of its restricted use.

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 an animal drug.

...
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 this 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.

Id. at 754. (citations omitted).

Therefore, the holding of the US Court of Appeals for the D.C Circuit is binding on the FDA. The Court held that risk - benefit analysis is a required, inherent part of the determination of "safe" under the FFDCA. Because risk - benefit analysis is inherent in the determination of safety under the FFDCA, "reasonable certainty of no harm," as applied by CVM, cannot be the standard because it fails to conduct the required analysis.

Furthermore, the US Supreme Court has recently held that risk benefit / analysis is inherent in the determination of "safe" under the several provisions of the FFDCA that require a determination of safety. *FDA v. Brown & Williamson*, 529 US 120, 140 (2000) ("Several provisions in the Act require the FDA to determine that the *product itself* is safe as used by consumers. That is, the product's probable therapeutic benefits must outweigh its risk of harm."). The courts that have addressed the issue have consistently held that a risk / benefit analysis is inherent to the process. When will CVM's policy comply with the courts' rulings?

iii. CVM ANALYSIS IS SUPERFICIAL

During discussion at the *Use of Antimicrobial Drugs in Food Animals and the Establishment of Regulatory Thresholds on Antimicrobial Resistance*, workshop held by CVM in January 2001, and in follow-up, CVM panelist, Linda Horton, contended that CVM did not have to perform a risk / benefit analysis when determining whether a new animal drug is "safe" under

FFDCA, and gave as reference a document titled *PRECAUTION IN U.S. FOOD SAFETY DECISIONMAKING*: Annex II to the United States' National Food Safety System Paper. This document can be found on the www.foodsafety.gov website. The Precaution paper does not support the position taken by CVM. A single footnote in the document states: "As to veterinary drugs, FDA's position has long been that, in its decision making, the agency is precluded from cost-benefit analysis. See FDA's Decision banning DES, 44 Fed. Reg. 54852 (1979), and FDA's regulation banning gentian violet as an additive in animal feed or as an animal drug, 56 Fed. Reg. 40502 (1991) (citing the American Textiles Manufacturers case)." *Id.* at note 212.

The footnote reference to the DES decision is interesting, as it was in the DES cases (the *Hess & Clark* and *Rhone-Poulenc* cases discussed above) that the D.C. Circuit rejected CVM's position, concluding that risk / benefit analysis is an inherent part of the determination of whether a new animal drug is "safe" under the FFDCA. Further, reliance on the *American Textile Manufacturers* case is also misplaced, as discussed below.

iv. CVM POSITION ON COST / BENEFIT ANALYSIS IS INCORRECT

CVM has long taken the position that cost / benefit analysis is not part of its inquiry under the FFDCA. *See e.g.* 56 Fed. Reg. 41902 (1991) (Nitrofurans withdrawal action). In that action CVM stated that cost/benefit considerations are irrelevant under the general safety clause of the FFDCA, and that *American Textiles Manufacturers Institute v. Donovan*, 452 U.S. 490 (1981) is "ample authority" for the proposition that clauses like the FFDCA's general safety clause "do not permit, much less invite, cost/benefit analysis." Illustrative of the overall problem with the FDA analysis, it bolsters its position by referencing language from the FDA DES decision that was rejected a decade before by the D.C. Circuit. 56 Fed. Reg. at 41902 at n.5.

CVM's reliance on *American Textiles Manufacturers Institute* is misplaced. The issue in that case was whether OSHA's organic statute required an economic cost / benefit analysis in terms of the economic cost to the regulated industry versus the benefits derived by a cotton dust standard. *American Textiles Manufacturers Inst.* 452 US at 506. The holding in that case was that a cost benefit analysis was not required because feasibility analysis was required, as mandated by Congress. *Id.* at 509. The analysis of whether the cost incurred by the regulated industry in complying with a particular regulation is outweighed by the benefits produced by the regulation is a qualitatively different inquiry than whether the benefits produced by a drug outweigh the cost of its restricted use. In the context of pharmaceuticals, an analogous inquiry to the one in *American Textiles Manufacturers Inst.* would occur if the industry challenged a regulation requiring a particular type of study by saying the agency didn't take into account the costs incurred by the industry in running the studies versus the amount of beneficial information learned from them. In a case where the FDA was a party, the US Court of Appeals for the First Circuit indicated that reliance on the *American Textiles Manufacturers Inst.* case in the context of interpreting the FFDCA was misplaced. *Commonwealth of Massachusetts v. Hayes*, 691 F.2d 57, n.4.

2. CVM MUST CONSIDER THE INTERACTION BETWEEN THE FFDCA, THE MEAT INSPECTION ACT, AND THE POULTRY PRODUCTS INSPECTION ACT

The FDA regulates the approval of new animal drugs under the FFDCA. The USDA regulates the slaughter and processing of livestock and poultry under the Meat Inspection Act and the Poultry Products Inspection Act. Under the FFDCA, CVM determines whether a new animal drug has been shown to be "safe." One of the statutory factors for consideration of safety is the "probable consumption of such drug and of any substance formed in or on food because of the use of such drug." *See* 21 USC § 360b(d). In the NOOH, CVM states that it views resistant campylobacter bacteria to be "substances" formed in or on one food due to the use of the new animal drugs in question. 65 Fed.Reg. at 64956. That is, they intend to consider whether the drug is safe based upon the presence of certain levels of resistant bacteria as contaminants to raw meat and poultry. CVM's proposed method for the consideration of the safety of these antimicrobial new animal drugs is directly dependent upon slaughter processes regulated by USDA. The incidence of bacterial contamination on meat and poultry carcasses is directly related to programs established and regulated by the USDA (e.g. HAACP). CVM cannot operate in a vacuum. It must consider the interaction between the FFDCA, the Meat Inspection Act and the Poultry Products Inspection Act, because with respect to many products, a veterinary drug sponsor will, in effect, be controlled by performance standards established by the USDA.

A. MEAT INSPECTION ACT AND POULTRY PRODUCTS INSPECTION ACT

The Meat Inspection Act requires the USDA to inspect all meat food products derived from cattle, sheep, swine, goats and equines prepared in any slaughtering, meat-canning, salting, packing, rendering, or similar establishments. 21 USC § 606. Products found not to be adulterated are stamped "inspected and passed." *Id.* This means that products stamped "inspected and passed" have been found not to bear or contain any poisonous or deleterious substance which may render it injurious to health, or that the quantity of any substance does not ordinarily render it injurious to health. 21 USC § 601(m). Likewise, the Poultry Inspection Act prohibits the sale of any poultry products unless they have been inspected and passed as not adulterated. 21 USC 458(a)(2). This means that products inspected and passed have been found not to bear or contain any poisonous or deleterious substance which may render it injurious to health, or that the quantity of any substance does not ordinarily render it injurious to health. 21 USC 453(g). In the context of food, the use of the terms "adulterated" and "substance" are consistent between the Meat Inspection Act, the Poultry Products Inspection Act and the FFDCA. *Compare* 21 USC § 342, 21 USC § 453(g), and 21 USC § 601(m). Moreover, courts will interpret the same language from these statutes to have the same meaning. *See Supreme Beef Processors, Inc. v. USDA*, 113 F. Supp. 2d 1048, 1052 (N.D. Tex. 2000) (In order to interpret the Meat Inspection Act, the court cited to case interpreting identical definition of the term "adulterated" in the FFDCA).

B. CVM AND USDA CONFLICT ON THE MEANING OF THE SAME TERMS IN THE SAME CONTEXT

The USDA does not consider the mere presence of bacterial pathogens (except for *E. coli* 0157:H7 in certain circumstances) regardless of antimicrobial resistance patterns, to cause raw meat or poultry to be adulterated. Final Rule, Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38835 (1996) (“Therefore, FSIS has not taken the position in this rulemaking that some amount of a pathogen necessarily renders a raw meat or poultry product unsafe and legally adulterated.”). It is FSIS policy to label “inspected and passed” raw meat and poultry products with the known or suspected presence of some pathogenic bacteria. *Id.* at 38852.

By operation of law, the marketing of raw meat and poultry products that contain “resistant” bacteria (i.e. those with particular resistance patterns) necessarily means that the USDA has, by virtue of labeling it “inspected and passed,” made a determination that either (1) resistant bacteria on raw meat or poultry are not “substances;” (2) resistant bacteria on raw meat or poultry are not substances that may be injurious to health; or (3) resistant bacteria on raw meat or poultry are not substances present in quantities that ordinarily render it injurious to health. As CVM has contended that the fluoroquinolones approved for use in chickens and turkeys are no longer shown to be safe due to the existence of some level of resistant *Campylobacter* bacteria contaminating raw chickens products, where the poultry at issue was marked “inspected and passed” and sold into the food supply, CVM and USDA are necessarily in conflict over the use of the same statutory terms in the same context. CVM considers these drugs unsafe due to the presence of a substance, resistant bacteria, that USDA has determined is either not a substance, not a substance injurious to health, or not a substance present in quantities ordinarily injurious to health. This conflict is not removed by CVM simply asserting that its authority is found in a different statute than USDA’s. First, the Supreme Court has stated that it is a classic judicial task to reconcile many laws enacted over time to have them make sense in combination. *FDA v. Brown & Williamson*, 529 U.S. 120, 143 (2000). Therefore, the acts will eventually be interpreted to make sense in concert. Second, as federal courts will interpret the same language under the FFDCA and the Meat Inspection Act and Poultry Inspection Acts the same, CVM must address the implications of arriving at differing conclusions than USDA when interpreting how to handle “substances” on meat and poultry. Third, CVM is attempting to determine the safety of veterinary antibiotics based upon the resistance patterns of bacterial contaminants isolated from USDA regulated facilities. The presence of contaminants is directly related to processes regulated by USDA under the Meat Inspection and Poultry Inspections Acts. Therefore, CVM must consider the interactions between the Meat Inspection Act, the Poultry Products Inspection Act, as well as the implications and ramifications of conflicting interpretations. How can CVM find that these veterinary antibiotics are not safe based on a substance formed in or on food due to the use of an animal drug, where the USDA, who regulates the animal product, has determined that the same “substance” on the same food is either not a substance, not injurious to health or nor present in a quantity that is ordinarily injurious to health?

3. Withdrawal of NOOH

The NOOH seeking the removal of veterinary fluoroquinolones for use in Chickens and Turkeys from the market should be withdrawn by CVM. A thorough discussion of the numerous

flaws within the NOOH can be found in the comments of the Animal Health Institute, the Bayer Corporation, the American Veterinary Medical Association, and a host of others who submitted substantive comments to the docket. Together, these comments demonstrate that the NOOH should be withdrawn.

However, several legal and policy issues compel withdrawal of the NOOH. First, as discussed above, it relies upon an improper use of the "reasonable certainty of no harm." Therefore, any conclusion reached in the NOOH is fatally flawed. Second, CVM presented zero data regarding the turkey approvals. Seeking the withdrawal of a product from the marketplace, i.e. the turkey claim, while supplying absolutely zero data and no discussion is the very definition of an arbitrary and capricious action. Finally, from a policy perspective, the FDA has worked for more than two years towards establishing regulatory thresholds for veterinary antibiotics used in food producing species. Yet, CVM chose to issue the NOOH before any public discussion of appropriate levels of risk or meaningful discussion of risk standards was held. CVM has not defined the thresholds that, according to it, will establish acceptable levels of risk. How can CVM be in a position to, in effect, set a regulatory threshold for veterinary fluoroquinolones in chickens and turkeys, before the process designed to figure out how to appropriately set such regulatory thresholds is complete?

C. ENVIRONMENTAL IMPACT

This petition is categorically excluded from submission of an environmental assessment

D. ECONOMIC IMPACT

If requested we will provide information about economic impact.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

Sincerely,

Kent D. McClure, DVM, JD