DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857



**MEMORANDUM**

**Date:** November 12, 2003

**To:** Docket No. 00N-1571 (Enrofloxacin for Poultry)

**From:** Counsel for the Commissioner,
Office of the Chief Counsel

Pursuant to 21 CFR 10.55(d)(3), the attached document is being provided by the Office of the Commissioner of the Food and Drug Administration (FDA) to Docket 00N-1571, to all participants, and the presiding officer.

The attached document is an email transmission and a redacted copy of one attachment, a draft entitled "GFI#152 Questions and Answers" on antimicrobials that was provided to the Office of the Commissioner by the Center for Veterinary Medicine, and was sent to the persons named in the email transmission on October 17, 2003.

## Jones, Rae

**From:** Jones, Rae
**Sent:** Friday, October 17, 2003 5:45 PM
**To:** McClellan, Mark, M.D.; Crawford, Lester, D.V.M.; Pitts, Peter; Reuther, Mary-Lacey; Sachdev, Amit; Troy, Daniel; Gottlieb, Scott; Weinshenker, Jeffrey; Bachorik, Lawrence L; Stone, Bradford; Cruzan, Susan M
**Cc:** Crim, Carol H; Sheehy, Janice; Wesley, Karen V
**Subject:** CLEARANCE NEEDED MONDAY, OCTOBER 20TH ON ANTIMICROBIAL Q&As & POWER POINT PRESENTATION

**Follow Up Flag:** Follow up
**Flag Status:** Flagged

PLEASE PROVIDE YOUR COMMENTS BY MONDAY, OCTOBER 20TH ON THE ATTACHED ANTIMICROBIAL Q&As & POWER POINT PRESENTATION.


GFI 152 Questions and Answers....


GFI152 rollout.ppt

# GFI #152 Questions and Answers

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**How does this guidance work?**

The guidance is presented as a tool for animal drug sponsors to use when they want to prove to FDA that an antimicrobial drug can be used to treat animals without creating a threat to public health through the creation of resistant bacteria. The key to the guidance is a risk assessment. The drug sponsor uses data to determine, first, whether the antimicrobial drug will first create resistant bacteria in the animal being treated, second, whether the resistant bacteria will infect humans, and, third, whether the bacteria will cause medical problems. For example, FDA has already determined that the use of an antimicrobial product, a fluoroquinolone, in water used to treat chickens and turkeys meets all three requirements. It creates resistant bacteria, *Campylobacter*, that are transferred to humans and can cause intestinal illness. In addition, while physicians would typically treat such cases with a fluoroquinolone, they are not able to in this case because the bacteria have already acquired resistance to the drug because the drug was used in poultry. The guidance document, which did not exist when fluoroquinolones were

first reviewed by FDA, would score the risk from fluoroquinolones high, so that FDA could not now approve them for use in poultry as a water soluble product.

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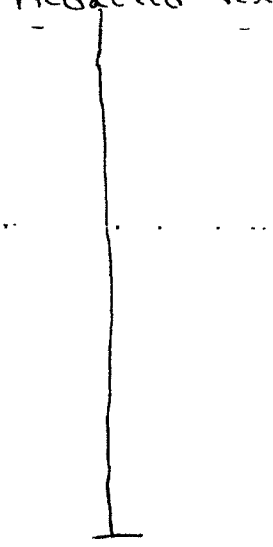

**Can you give me an example of a drug that has a high risk estimation? What have you done about that drug?**

The fluoroquinolone mentioned earlier is a good example. FDA has filed a petition to remove the product from the market. We cannot talk about products that have been presented to FDA for review and were not approved. But if an antimicrobial scores high under the guidance, and the drug sponsor can't show us how to mitigate the risk to humans, the product would not be approved.

It is important to note that the way a product is used will make a difference in whether the product will be acceptable. For instance, although FDA has proposed to remove a poultry fluoroquinolone product from the market, FDA has approved another fluoroquinolone product for use in feedlot cattle. That approval is for single animal treatment and is an injectable product. The difference between the cattle product and the poultry product is the formulation; the cattle product is used to treat individual animals whereas the poultry product was delivered in water to an entire house of chickens. Therefore, the selection pressure is much greater with the poultry use.

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**Will this guidance apply to the Bayer's drug that you are trying to remove from the market?**

Yes. The enrofloxacin product described earlier is the Bayer product we have proposed to remove from the market.

Incidentally, we are concerned with the product used in water to treat poultry. Bayer has a separate fluoroquinolone product, Baytril 100, that was created to be used in beef cattle. The product would not score as high for risk as the poultry product because exposure levels are substantially lower.

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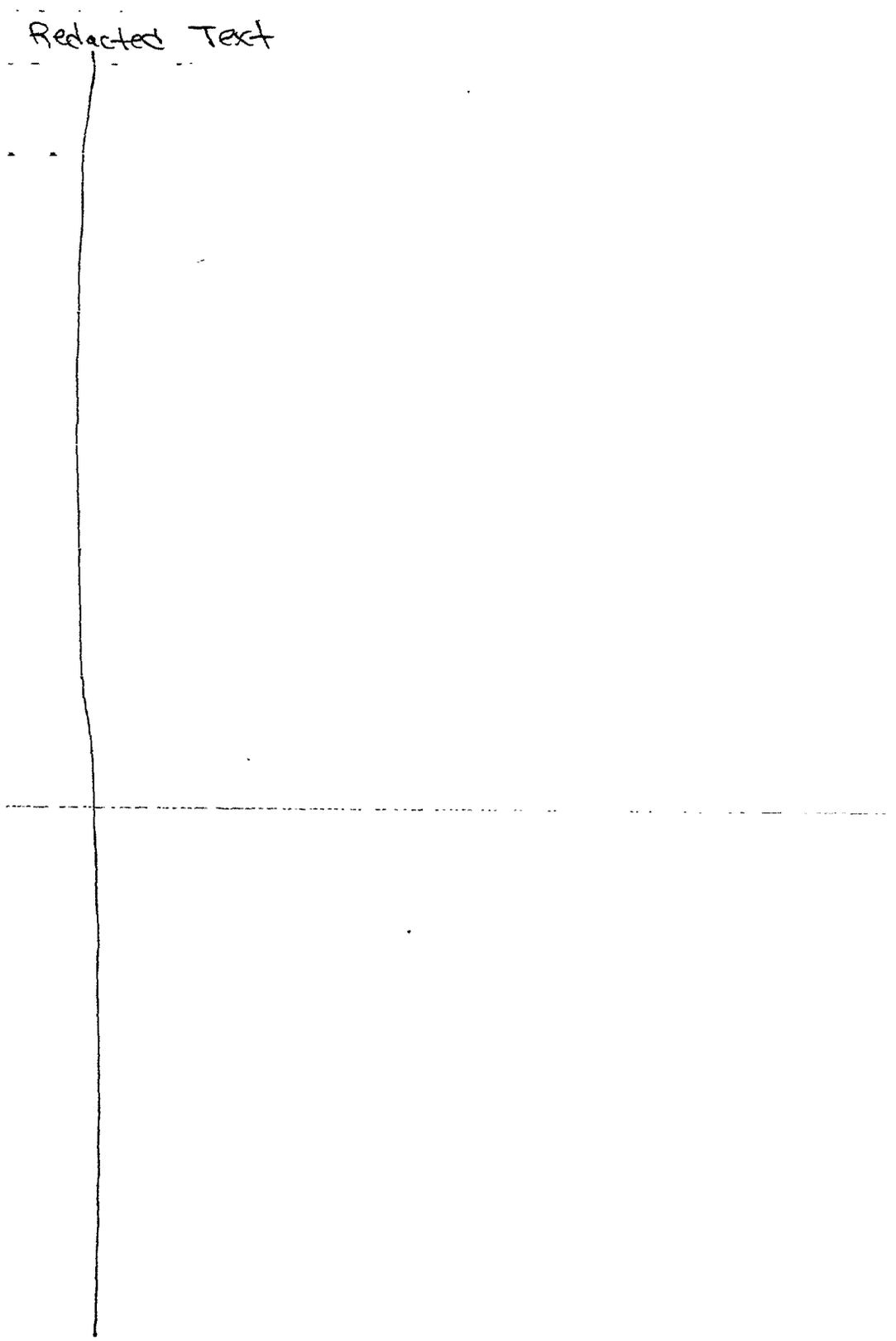
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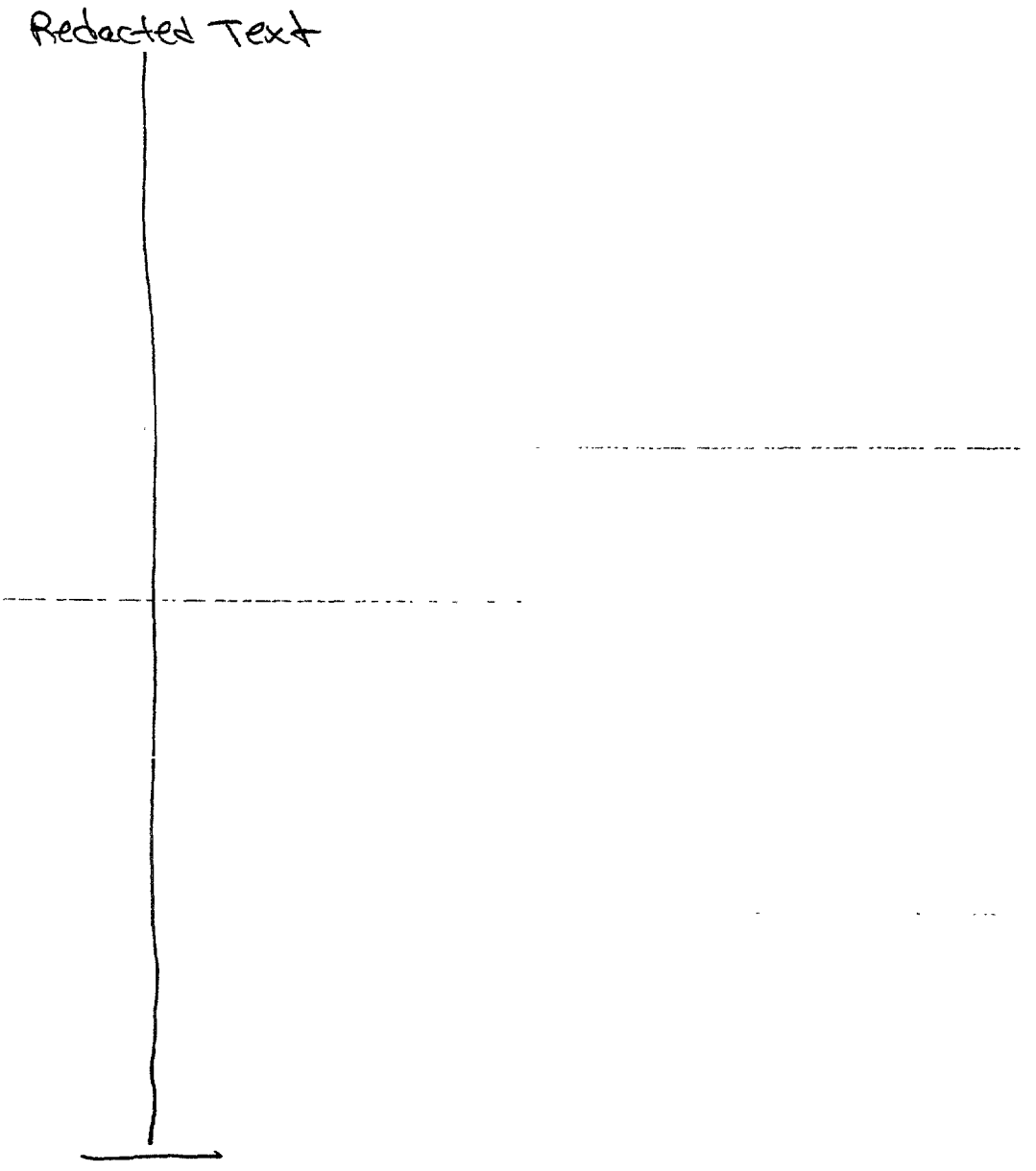
Redacted Text

Docket No. 00N-1571

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**CERTIFICATE OF SERVICE**

I hereby certify that two copies of the foregoing Memorandum from Counsel for the Commissioner and attachments were hand delivered on November 12, 2003, to:

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

I also certify that a copy of the Memorandum and attachment were hand delivered and e-mailed to on November 12, 2003, to:

The Office of the Administrative Law Judge (HF-3) (ddavidso@oc.fda.gov)
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and

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I also certify that a copy of the Memorandum and attachment were sent by U.S. mail, postage prepaid, and e-mailed on November 12, 2003, to:

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DATED: 11/12/03

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