



Congress of the United States
Washington, DC 20515

July 22, 2004

Dr. Lester M. Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

We are writing to express our concern at the process by which FDA's Center for Veterinary Medicine (CVM) is proposing to withdraw approval for the use of a fluoroquinolone (enrofloxacin) in poultry. We strongly support FDA's public-health mission, but we also believe the long-term consequences of banning fluoroquinolone use in poultry requires the agency to "go the extra mile" in ensuring the scientific validity of its action.

When the agency approved fluoroquinolone use in poultry in 1996, it was the result of one of the most exhaustive animal drug reviews in CVM's history. Safeguards were put in place to ensure the drug's safe, effective use and to monitor potential increases in antibiotic resistance among animals and humans. An additional protection was added in 1997, when CVM banned "extra-label" use of fluoroquinolones. As a result of these safeguards – and the high cost of the drugs – fluoroquinolones are among the most sparingly used animal drugs in this country. Reliable estimates indicate less than 2 percent of all chickens and only about 4 percent of all turkeys are treated with the drug. However, when the drug is used in poultry production, it is absolutely essential to protecting the health of the birds.

Resistance data since the drugs' approval indicate the incidence in humans of campylobacteriosis – the illness of most concern to CVM – decreased from 2.4 million cases to 1.4 million cases the first three years the drug was in use. More significantly, the incidence of fluoroquinolone-resistant *Campylobacter* infections in humans decreased from 3.28 to 2.62 cases per 100,000 population between 1997 and 2001. Finally, there are effective alternatives available to treat campylobacteriosis in humans, while there are almost no practical alternatives to treat the poultry diseases for which fluoroquinolones are prescribed.

Despite this evidence, CVM in 2000 began to move toward banning fluoroquinolone use in poultry. After a lengthy hearing, an FDA Administrative Law Judge's Initial Decision this March ruled in favor of CVM and against the manufacturer of the only remaining fluoroquinolone product on the market. The manufacturer and CVM have filed exceptions to the judge's findings, and both parties will respond to those exceptions by mid July. After that, it will be up to you to decide whether to accept the judge's Initial Decision and withdraw approval for the drug or to take some other course of action.

We believe the circumstances of the case justify setting aside the wishes of FDA's Center for Veterinary Medicine and the findings of an Administrative Law Judge. There is ample

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evidence to indicate the Administrative Law Judge made erroneous findings on such key matters as the probability of transferring resistant *Campylobacter* infections from poultry to humans, the incidence of fluoroquinolone-resistant campylobacteriosis in humans, the duration of illness for people who contract resistant campylobacteriosis and the public health benefits realized from the use of fluoroquinolones in poultry.

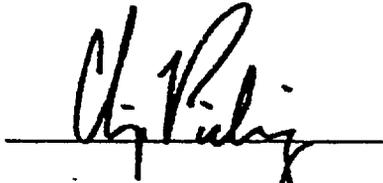
Finally, the judge reaches the very surprising conclusion that fluoroquinolone use in turkeys may be withdrawn based on studies that were conducted almost exclusively on chickens. The judge used this data to rule the effect of fluoroquinolone use was the same on both species. CVM long has held that no drug for turkeys may be approved based solely on data from chickens, or vice versa. CVM presented no data on turkeys at the time it moved to ban fluoroquinolone use in poultry and presented only scant evidence relating to turkeys during the hearing process. By allowing the drug to be banned for one species based on data from another species creates an egregious double standard and is a blatant abuse of regulatory authority.

For all of these reasons listed above, we strongly urge you to set aside the judge's decision and insure a thorough and objective review of all the scientific evidence to weigh the risks, along with the benefits, from the continued use of fluoroquinolones in poultry.

We appreciate your consideration of this request, and we look forward to your response.

Sincerely,

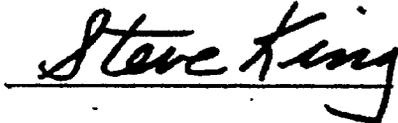
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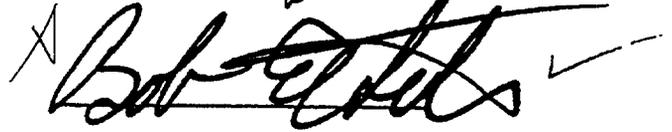
Devin Nunes



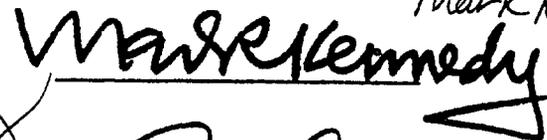
John A. Boehner
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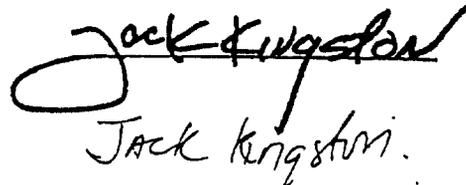
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