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

2004-4369

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,

harles W "Chip" Pickering, Jr

Bob Riggs

Sam Graves

Mark Kennedy

Steve King

Devin Nunes

Baron P. Hill

John A. Boehner
3508

Jack Kingston

20515-1009 Nathan Deal
Nathan Deal

Roy Blunt 1507
Roy Blunt

Charlie Norwood
Charlie Norwood

Mike McIntyre
Mike McIntyre

Eric I Cantor Eric Cantor

Mike Ross
Mike Ross

Albert R. Wynn Albert R. Wynn

Max Burns ✓ 1012
Max Burns

✓

Jim Marshall
Jim Marshall

Marion Berry ? Marion Berry

John Kline X

2401 Roger F. Wicker
Roger F. Wicker

Jim Petri Thomas E Petri

Jerry Moran

Sanford D. Bishop, Jr
Sanford D. Bishop, Jr

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Charles W. "Chip" Pickering, Jr.
House of Representatives
Washington, D.C. 20515-2403

Dear Mr. Pickering:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

An Administrative Law Judge (ALJ) under regulations found at 21 CFR Part 12 conducts FDA's formal hearings. These regulations reflect provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act and the Administrative Procedures Act that apply to formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of new animal drug approval (NADA) 140-828, pursuant to section 512(e)(1)(B) of the FD&C Act. CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register* on October 31, 2000. Bayer filed a request for a hearing on November 29, 2000, and the Commissioner of FDA agreed, publishing a notice of hearing on February 20, 2002. Subsequently, joint stipulations and revised joint stipulations were submitted on September 20 and December 24, 2002, respectively. Documentary evidence and written direct testimony was submitted by CVM on December 9, 2002, and by Bayer and the Animal Health Institute (AHI) on December 13, 2002. Oral hearing for cross-examination of witnesses was held between April 28 and May 27, 2003. Briefs were filed on July 18, 2003, and reply briefs on August 15, 2003. The initial decision of the ALJ was issued on March 16, 2004, and the parties filed exceptions to the initial decision on May 17, 2004. On July 16, 2004, CVM filed its reply to the Bayer and AHI exceptions, and Bayer and AHI filed their reply to CVM's exceptions.

A public docket (00N-1571) was established at the time the NOOH was published in October 2000. Documents related to the hearing, including the NOOH, referenced scientific studies, correspondence, briefs, the initial decision of the ALJ, and subsequent filings by CVM and Bayer and AHI can be found in the public docket.

Thank you again for contacting us about this matter. We hope this information is helpful. If we can be of further assistance, please let us know. An identical letter has been sent to the co-signers of your letter.

Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Marion Berry
House of Representatives
Washington, D.C. 20515-0401

Dear Mr. Berry:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Charlie Norwood
House of Representatives
Washington, D.C. 20515-1009

Dear Mr. Norwood:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Jerry Moran
House of Representatives
Washington, D.C. 20515-1601

Dear Mr. Moran:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Mike McIntyre
House of Representatives
Washington, D.C. 20515-3307

Dear Mr. McIntyre:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Jim Marshall
House of Representatives
Washington, D.C. 20515-1003

Dear Mr. Marshall:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Sanford D. Bishop, Jr.
House of Representatives
Washington, D.C. 20515-1002

Dear Mr. Bishop:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Thank you again for contacting us about this matter. We hope this information is helpful. If we can be of further assistance, please let us know. An identical letter has been sent to the co-signers of your letter.

Sincerely,

Patrick O. McCoy

Patrick Ronan
For Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Roy Blunt
House of Representatives
Washington, D.C. 20515-2507

Dear Mr. Blunt:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). . Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick O. McCay

Patrick Ronan
for Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Thomas E. Petri
House of Representatives
Washington, D.C. 20515-2302

Dear Mr. Petri:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Sam Graves
House of Representatives
Washington, D.C. 20515-2506

Dear Mr. Graves:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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The Center for Veterinary Medicine (CVM) proposed to withdraw approval of new animal drug approval (NADA) 140-828, pursuant to section 512(e)(1)(B) of the FD&C Act. CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register* on October 31, 2000. Bayer filed a request for a hearing on November 29, 2000, and the Commissioner of FDA agreed, publishing a notice of hearing on February 20, 2002. Subsequently, joint stipulations and revised joint stipulations were submitted on September 20 and December 24, 2002, respectively. Documentary evidence and written direct testimony was submitted by CVM on December 9, 2002, and by Bayer and the Animal Health Institute (AHI) on December 13, 2002. Oral hearing for cross-examination of witnesses was held between April 28 and May 27, 2003. Briefs were filed on July 18, 2003, and reply briefs on August 15, 2003. The initial decision of the ALJ was issued on March 16, 2004, and the parties filed exceptions to the initial decision on May 17, 2004. On July 16, 2004, CVM filed its reply to the Bayer and AHI exceptions, and Bayer and AHI filed their reply to CVM's exceptions.

A public docket (00N-1571) was established at the time the NOOH was published in October 2000. Documents related to the hearing, including the NOOH, referenced scientific studies, correspondence, briefs, the initial decision of the ALJ, and subsequent filings by CVM and Bayer and AHI can be found in the public docket.

Thank you again for contacting us about this matter. We hope this information is helpful. If we can be of further assistance, please let us know. An identical letter has been sent to the co-signers of your letter.

Sincerely,

Patrick O. McCay

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Mike Ross
House of Representatives
Washington, D.C. 20515-0404

Dear Mr. Ross:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Roger F. Wicker
House of Representatives
Washington, D.C. 20515-2401

Dear Mr. Wicker:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Devin Nunes
House of Representatives
Washington, D.C. 20515-0521

Dear Mr. Nunes:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Baron P. Hill
House of Representatives
Washington, D.C. 20515-1409

Dear Mr. Hill:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick O. McCarey

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Mark Kennedy
House of Representatives
Washington, D.C. 20515-2306

Dear Mr. Kennedy:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick O. McCaey

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Steve King
House of Representatives
Washington, D.C. 20515-1505

Dear Mr. King:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Jack Kingston
House of Representatives
Washington, D.C. 20515-1409

Dear Mr. Kingston:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable John P. Kline
House of Representatives
Washington, D.C. 20515-2302

Dear Mr. Kline:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

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Sincerely,

Patrick O. Ronan

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable John A. Boehner
House of Representatives
Washington, D.C. 20515-3508

Dear Mr. Boehner:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick O. McGarry

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Max Burns
House of Representatives
Washington, D.C. 20515-1012

Dear Mr. Burns:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

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The Center for Veterinary Medicine (CVM) proposed to withdraw approval of new animal drug approval (NADA) 140-828, pursuant to section 512(e)(1)(B) of the FD&C Act. CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register* on October 31, 2000. Bayer filed a request for a hearing on November 29, 2000, and the Commissioner of FDA agreed, publishing a notice of hearing on February 20, 2002. Subsequently, joint stipulations and revised joint stipulations were submitted on September 20 and December 24, 2002, respectively. Documentary evidence and written direct testimony was submitted by CVM on December 9, 2002, and by Bayer and the Animal Health Institute (AHI) on December 13, 2002. Oral hearing for cross-examination of witnesses was held between April 28 and May 27, 2003. Briefs were filed on July 18, 2003, and reply briefs on August 15, 2003. The initial decision of the ALJ was issued on March 16, 2004, and the parties filed exceptions to the initial decision on May 17, 2004. On July 16, 2004, CVM filed its reply to the Bayer and AHI exceptions, and Bayer and AHI filed their reply to CVM's exceptions.

A public docket (00N-1571) was established at the time the NOOH was published in October 2000. Documents related to the hearing, including the NOOH, referenced scientific studies, correspondence, briefs, the initial decision of the ALJ, and subsequent filings by CVM and Bayer and AHI can be found in the public docket.

Thank you again for contacting us about this matter. We hope this information is helpful. If we can be of further assistance, please let us know. An identical letter has been sent to the co-signers of your letter.

Sincerely,

Patrick O. McGeary

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Eric I. Cantor
House of Representatives
Washington, D.C. 20515-4607

Dear Mr. Cantor:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Thank you again for contacting us about this matter. We hope this information is helpful. If we can be of further assistance, please let us know. An identical letter has been sent to the co-signers of your letter.

Sincerely,

Patrick O. McCoy

Patrick Ronan
For Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 1 7 2004

The Honorable Nathan Deal
House of Representatives
Washington, D.C. 20515-1010

Dear Mr. Deal:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick O. McCoy

Patrick Ronan
For Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Bob Etheridge
House of Representatives
Washington, D.C. 20515-3302

Dear Mr. Etheridge:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Albert R. Wynn
House of Representatives
Washington, D.C. 20515-2004

Dear Mr. Wynn:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 18 2004

The Honorable Mike Pence
House of Representatives
Washington, D.C. 20515-1406

Dear Mr. Pence:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 18 2004

The Honorable Chris Chocola
House of Representatives
Washington, D.C. 20515-1402

Dear Mr. Chocola:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

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Sincerely,

Patrick Ronan
Assistant Commissioner
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(Docket No. 00N-1571)