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**MCDERMOTT, WILL & EMERY**

August 27, 2002

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

Re: In the Matter of Notice of Hearing: Proposal to Withdraw  
Approval of New Animal Drug Application for Enrofloxacin  
for Poultry ("Enrofloxacin Hearing")  
FDA Docket: 00N-1571

Dear Sir/Madam:

Enclosed for filing please find an original and two copies of a Joint Consent Motion to Extend Deadline for Submission of Joint Stipulations. Please return a file-stamped copy in the enclosed self-addressed stamped envelope.

Please call with any questions.

Sincerely,



Gregory A. Krauss

GAK:jeh  
Enclosures

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

In the Matter of:

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

**JOINT CONSENT MOTION TO EXTEND DEADLINE  
FOR SUBMISSION OF JOINT STIPULATIONS**

On April 10, 2002, Administrative Law Judge Davidson issued an Order establishing a Schedule of Due Dates (the "Scheduling Order") in the above-captioned hearing. The Scheduling Order establishes a September 16, 2002 deadline for the submission of joint stipulations. By Joint Consent Motion, Bayer Corporation ("Bayer") and the Center for Veterinary Medicine ("CVM"), with the assent of the Animal Health Institute ("AHI")<sup>1</sup>, respectfully request that the schedule be amended to allow the Submission of Joint Stipulations on September 20, 2002.

**The Present Joint Stipulation Deadline Falls On Yom Kippur**

The current Scheduling Order sets September 9, 2002 as the date for Exchange of Proposed Stipulations and September 16, 2002 as the deadline for Submission of Joint Stipulations. This year, the Jewish holiday of Yom Kippur falls on September 16, 2002.<sup>2</sup> Because the joint stipulation deadline conflicts with Yom Kippur, counsel for CVM contacted

<sup>1</sup> On August 26, 2002, counsel for Bayer, Gregory A. Krauss, discussed the within Motion with Kent D. McClure, counsel for participant AHI. Counsel for AHI assented to the extension sought herein.

<sup>2</sup> Yom Kippur begins on sundown August 15, 2002, and ends on August 16, 2002 at sundown.

counsel for Bayer to discuss a proposal to amend the due date. Counsel for the parties agreed to jointly propose by motion an extension of the joint stipulation deadline to September 20, 2002. The parties believe that the extension of this deadline by four days will not result in any undue delay of the proceedings.

**Extending the Deadline Will Give the Parties Additional Time to Discuss and Agree to Joint Stipulations**

Counsel for Bayer and CVM discussed *shortening* the deadline for joint stipulations to September 13, 2002 in light of the conflict with Yom Kippur. This option is impractical, however, because it would allow only 4 days after the September 9, 2002 exchange (one of which is the September 11th anniversary) to discuss, negotiate and agree to joint stipulations. The parties agreed, therefore, that a short *extension* is in the best interest of the parties and of the hearing officer. The parties believe that joint stipulations will be the best opportunity to narrow the scope of testimony presented at the hearing. Counsel for the parties agree that having the additional time will increase the chances that the parties will reach agreement on more of the proposed stipulations. Counsel also agree that extending the deadline for submission of joint stipulations by four days is a reasonable proposal that will not prejudice any party or unreasonably delay the proceeding.

**Parties May Request Extensions of Time and the Regulations Permit the ALJ To Grant Such Requests**

The March 22, 2002 Order in this matter specifically provides that the parties, either on their own or jointly, may seek an extension of the Schedule:

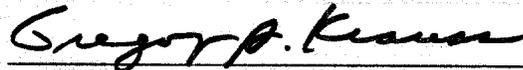
Requests for extensions of time must be submitted in writing at least five full working days before the due date. However, unopposed requests for extensions of time may be made at any time up to and including the day prior to the due date.

March 22, 2002 Order at 2. Furthermore, under 21 CFR § 12.70, the presiding officer has the authority to set the time for pleadings, and rule on motions and other procedural matters. See 21 CFR § 12.70(i) & (j). Here, the parties have submitted a timely unopposed joint motion more than three weeks before the joint stipulation deadline. Thus, the ALJ has both the authority to grant such a motion, and ample time to consider this joint proposal.

**Conclusion**

Bayer and CVM jointly propose a short extension in the joint stipulation deadline, because the current deadline falls on Yom Kippur. A modification of the due date will not prejudice any party or participant, will not result in any unreasonable delay of the proceeding and will allow the parties additional time to negotiate joint stipulations. The Parties respectfully request, therefore, that the proposed change to the Schedule above should be adopted.

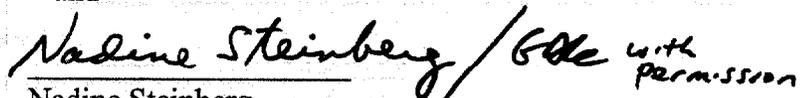
Respectfully submitted,



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James H. Sneed  
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*Attorneys for Bayer*

and



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Counsel for the Center for Veterinary Medicine  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20850  
(301) 827-5050

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the Joint Consent Motion to Extend Deadline For Submission of Joint Stipulations was sent via e-mail and via first-class mail, postage pre-paid this 27th day of August 2002, to:

Nadine R. Steinberg, Esquire  
Food and Drug Administration  
Office of General Counsel (CGF-1)  
5600 Fischers Lane, Room 7-77  
Rockville, MD 20857

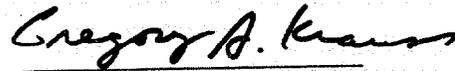
and was mailed, via first-class mail, postage pre-paid to:

Kent D. McClure  
Animal Health Institute  
1325 G Street, N.W., Suite 700  
Washington, D.C. 20005

Dockets Management Branch (HFA - 305) - FDA  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20857

and was sent via e-mail and via facsimile to:

Honorable Daniel J. Davidson  
Administrative Law Judge  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, Maryland 20857

  
\_\_\_\_\_  
Gregory A. Krauss

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

In the Matter of:

**Enrofloxacin for Poultry:  
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**FDA DOCKET: 00N-1571**

**ORDER**

UPON CONSIDERATION of the Joint Consent Motion to Extend the Deadline for Submission of Joint Stipulations, it is hereby

ORDERED that the Motion is GRANTED; and it is further

ORDERED that the schedule of due dates is modified to read as follows:

**Stipulations:**

9. Submission of Joint Stipulations

9/20/02

The remainder of the Schedule of Due Dates would remain as it appears in the April 10, 2002 Order.

DATED this the \_\_\_ day of August, 2002.

**Daniel J. Davidson**  
Administrative Law Judge



305

600 13th Street N.W.  
Washington, D.C. 20005-3096

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