

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

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In the Matter of:)

**Enrofloxacin for Poultry: Withdrawal
of Approval of Bayer Corporation's
New Animal Drug Application
(NADA) 140-828 (Baytril)**)
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**FDA DOCKET: 00N-1571
DATE: June 23, 2003**

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Center for Veterinary Medicine's Response to Bayer's Request for Clarification

The Center for Veterinary Medicine strongly disagrees with Bayer Corporation's position concerning the status of proposed findings of fact for which no critique is provided. First, CVM disagrees with Bayer's portrayal of the purpose of submitting proposed findings of fact. CVM believes that there is a fundamental difference between stipulations and proposed findings of fact. Stipulations represent agreement among the parties; proposed findings are to assist the judge in reaching and writing a decision in a matter by identifying citations that the proposing party contends support such proposals. Until ruled upon, proposed findings of fact remain just that – proposed.

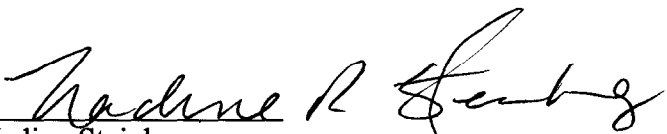
Second, CVM would be unduly prejudiced if the Administrative Law Judge accepted Bayer's reasoning in this matter. CVM's understanding was and remains reasonable and consistent with the April 10, 2002, Order. Silence does not and cannot mean consent without a clear understanding by both parties.

2000N-1571

RM046

Third, a post hearing brief should cite to the evidence. If Bayer's proposed findings of fact are actually supported by underlying evidence, there is no harm to Bayer, since Bayer can simply cite to the actual evidence. In fact, at the oral phase of the hearing (Hearing Transcript, p. 1128, L 8-15) the Administrative Law Judge ordered that the briefs refer to the evidence. CVM intends to cite to the evidence presented in this hearing, and urges the Administrative Law Judge to hold Bayer and the Animal Health Institute to this same standard.

Respectfully submitted:


Nadine Steinberg
Counsel for the Center for Veterinary Medicine

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) FDA DOCKET: 00N-1571

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) Enrofloxacin for Poultry: Withdrawal
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ORDER

By Request filed June 20, 2003, Bayer Corporation ("Bayer") requests clarification of the effect of any proposed finding of fact for which no critique was provided by the other participant. Bayer argues that such proposed findings should be deemed admitted. CVM disagrees, arguing that silence does not equate to admission and that the parties and participants should be required to cite to the actual evidence presented in this hearing. The purpose of submitting proposed findings of fact is not the same as submitted joint stipulations. Until ruled upon, proposed findings of fact are just that – proposed. Neither party or any participant should rely on proposed findings of fact in their briefs. Citation to the actual evidence in this hearing is required.

DATED this ____ day of June, 2003.

Daniel J. Davidson
Administrative Law Judge

Enrofloxacin Hearing

Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Response to Bayer's Request for Clarification was hand delivered this 23rd day of June, 2003, to:

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

I also certify that a copy of the Center for Veterinary Medicine's Response to Bayer's Request for Clarification was hand delivered and e-mailed this 23rd day of June, 2003, to:


The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy of the Center for Veterinary Medicine's Response to Bayer's Request for Clarification was mailed and e-mailed this 23rd day of June, 2003, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

Dated: 6/23/03


Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050