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 DATE: April 26, 2002

ORDER

By Motions filed April 15, 2002, Respondent Bayer Corporation requests reformulation of the hearing issues in this proceeding, objects to the 21 C.F.R § 12.85 submission by The Center For Veterinary Medicine (CVM), seeks to compel additional submissions and requests modification of the hearing schedule. Responses were filed by CVM on April 22, April 25 and April 25 respectively.

Review of the Motion to Reformulate Issues for Hearing and the response thereto leads to the conclusion that there is no compelling reason to modify the issues in this proceeding. The issues designated in the Notice of Hearing adequately reflect the statutory requirements. The motion will therefore be denied.

CVM has admitted certain deficiencies in its § 12.85 submissions and it will be ordered to fully comply with the provisions of that Rule. CVM requested 21 days to complete its review of the files. Considering the fact that such a review could have been undertaken months ago (even before the Notice of Hearing was issued), additional review time will be limited.

The schedule modification sought would provide for a sequential presentation of evidence with CVM going first. The consequences of simultaneous submissions of evidence are not as significant as Respondent claims. The provisions of 21 C.F.R § 12.85 combined with the additional discovery contemplated in this proceeding should make the evidence and contentions of the competing interests entirely transparent. Nevertheless, a limited modification to provide for sequential submissions* will not impact unduly on the remainder of the schedule. Accordingly, the motion will be granted in part.

* Under sequential submissions of evidence, only the side that goes first has a right to seek rebuttal based on the content of the opposing side's submission.

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