

**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: December 3, 2002

ORDER

By Motion filed November 22, 2002, Respondent Bayer Corporation seeks to add two witnesses (Drs. Robert Harris and Robert Livingston) pursuant to 21 C.F.R. § 12.92 (a)(2)(ii). On December 2, 2002 the Center for Veterinary Medicine (CVM) filed a response in opposition to the motion.

Lists of witnesses for this proceeding were originally exchanged on or before May 2, 2002. Under 21 C.F.R. § 12.92, additional witnesses may be later identified with the approval of the presiding officer on a showing that the witnesses were previously not reasonably available or that the relevance of the testimony could not have been reasonably foreseen.

It appears that the question concerning the availability of Dr. Livingston could have been resolved much earlier than it was. Accordingly, the information presented by Bayer as to the availability of Dr. Livingston is insufficient to permit the finding required by 21 C.F.R. § 12.92 (a)(2)(ii). The information presented by Bayer concerning Dr. Harris does not indicate exactly when his availability became known. Council for the Respondent has represented that another witness recently brought the relevance of Dr. Harris' expertise and his availability to Bayer's attention. Dr. Harris will therefore be provisionally added to Bayer's witness list pending an appropriate showing. Should Dr. Harris remain a witness in this proceeding, CVM will be given the opportunity for limited additional direct testimony at the oral hearing prior their witnesses being made available for cross-examination.

It is ORDERED that the Respondent's Motion filed November 22, 2002 is **Granted** provisionally with respect to the addition of Dr. Robert Harris as a witness in this proceeding and **Denied** with respect to the addition of Dr. Robert Livingston as a witness.

It is further Ordered that, on or before December 9, 2002 Respondent will submit a detailed explanation of how and when Bayer first became aware of Dr. Harris as a potential witness.

DATED this 31 day of December, 2002

s/s Daniel J. Davidson
Daniel J. Davidson
Administrative Law Judge