

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

_____))
In the Matter of:)) FDA DOCKET: 00N-1571
)) Date: June 25, 2003
Enrofloxacin for Poultry: Withdrawal)
of Approval of Bayer Corporation's)
New Animal Drug Application)
(NADA) 140-828 (Baytril))
_____))

On June 20, 2003, Respondent Bayer Corporation sought clarification of the April 10, 2002 Scheduling Order in this matter, particularly the provisions by which the participants were ordered to submit “numbered findings of fact, with record references, based on that which each participant believes the evidence has established” and then to submit “correspondingly numbered critiques of other participants’ numbered findings of fact.” Specifically, Bayer sought clarification of the effect any proposed finding of fact for which no critique was provided by the other participant.

Proposed findings of fact are simply that—proposed findings. Only the evidence on the record can form the basis of actual findings of fact. The purpose of the proposed findings of fact and critiques is to assist in the narrowing of issues and the ultimate determination of findings of fact. Failure to critique simply constitutes a missed opportunity to present an opposing view. Accordingly, there is no need for any additional clarification.

DATED this 25th day of June, 2003.

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

2000N-1571

OR 47