## 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-15 ) DATE: April 10, 2002 ) ) ) ) ) ) )	571
	ý	

## **ORDER**

The proposed schedule of pre-hearing and hearing requirements filed April 5, 2002 provides for an unduly prolonged process that would extend this proceeding well into the year 2004. Two areas of the proposed schedule appear to require the most significant amounts of time. One is from June to November of 2002. It provides for discovery proceedings in addition to that embodied in 21 CFR § 12.85. The other extends from May through December 2003 and contemplates two-stage evidentiary submissions and oral hearings for the purposes of cross-examination. Accordingly the proposed schedule has been modified, *inter alia*, in an attempt to minimize the time needed to complete the hearing stage of this proceeding.

nearing	g stage of this proceeding.				
Schedule of Due Dates			ZJ.		
1.	Motions to Modify issues for hearing:	4/15/02	$\stackrel{-}{\bigcirc}$		
2.	Responses to Motions to Modify for hearing:	4/22/02	P2:32		
Pre-Hearing Exchange:					
3.	Participant's submission of 12.85 documents:				
	Bayer Submission:	4/22/02			
	AHI's Submission:	5/6/02			

OON-1571

OR 2

4. Submission of additional 12.85 material if Motion to Modify issues for hearing is granted 5/20/02 Exchange of Witness Lists, CV's, and 5. **Prior Statements:** 5/20/02 6. Objection to witnesses based on qualifications: 6/03/02

## **Additional Discovery:**

During the period between June and September 2003 the participants are free to conduct additional discovery. The office of the Administrative Law Judge will not be involved unless there are disputes that requiring a formal ruling.

7.	Discovery Completed:	8/30/02		
Stipulations:				
8.	Exchange of Proposed Stipulations:	9/09/02		
9.	Submission of Joint Stipulations:	9/16/02		
Testimony/Exhibits, Cross Examinations, Dispositive Motions:				
10.	Submission of Written Direct Testimony/Exhibits:	12/09/02		
11.	Motions to Strike Testimony/Exhibits and/or Permission to Conduct Cross-examination:	1/27/03		
12.	Responses to Motions to Strike Testimony/Exhibits and/or Permission to Conduct Cross-examination:	2/10/03		
13.	Submission of numbered findings of fact, with record references, based on that which each participant believes the evidence has established.	3/17/03		
14.	Submission of correspondingly numbered critiques of other participants' numbered findings of fact.	4/14/03		
15.	Cross Examination of Witnesses:	4/28/03-5/09/		

4/28/03-5/09/03

A schedule for rebuttal, if necessary, and/or the Post-Hearing briefs will be established at the conclusion of the oral phase of the hearing.

Dated this \_\_\_\_\_\_ day of \_\_\_\_\_\_\_, 2002.

SO ORDERED:

Daniel J. Dayidson

Administrative Law Judge Food and Drug Administration

Rm. 9-57, HF-3 5600 Fishers Lane Rockville, MD 20857

Telephone: (301) 827-7120 FAX: (301) 594-6800