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MCDERMOTT, WILL & EMERY

April 14, 2003	0182
VIA HAND DELIVERY	£0 .
Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane (Room 1061) Rockville, Maryland 20852	/IPR 14 PA:33
Re: In the Matter of Notice of Hearing: Proposal to Withdraw Approval of New Animal Drug Application for Enrofloxacin for Poultry ("Enrofloxacin Hearing) FDA Docket: 00N-1571	ω

Dear Sir/Madam:

Enclosed for filing please find an original and two copies of Bayer's Request for Cross-Examination of CVM Witnesses.

Please call with any questions.

Sincerely,

Robert B. Nicholas

Enclosures

cc: Nadine Steinberg, Esquire (w/enclosure) Kent McClure, Esquire (w/enclosure)

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00N-1571

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

Estimated Time

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APR 14

PA:36

Date: April 14, 2003

<u>RESPONDENT BAYER CORPORATION'S</u> <u>REQUEST FOR CROSS-EXAMINATION</u>

Pursuant to the April 10, 2002 Order and Schedule of Due Dates in this proceeding, Respondent Bayer Corporation hereby requests the cross-examination of the following CVM witnesses and sets forth the estimated time for each. Based on review of CVM's critique of Bayer's and AHI's March 17, 2003, Proposed Findings of Fact, Bayer reserves the right to request modifications to this request.

CVM Witness

Frank M. Aarestrup, DVM, Ph.D. 2.0 hours Dr. Frederick J. Angulo 3.0 hours Timothy J. Barrett, M.S., Ph.D. 2.0 hours Dr. Mary J. Bartholomew 2.0 hours John Besser, B.S., M.S. 2.0 hours Hubert P. Endtz, M.D., Ph.D. 2.0 hours Maria-Liisa Hänninen 3.0 hours Wilma Froukje Jacobs-Reitsma, M.S, Ph.D. 1.0 hours Heidi Kassenborg, DVM, MPH 3.0 hours Stuart B. Levy, M.D. 1.0 hours Catherine M. Logue, Ph.D. 2.0 hours Patrick F. McDermott, M.S., Ph.D. 2.0 hours Jianghong Meng, DVM, Ph.D. 1.0 hours Dr. Kåre Mølbak, M.D., DMSc. 3.0 hours J. Glenn Morris, Jr., M.D., MPH & TM 1.0 hours

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Irving Nachamkin, Dr.P.H. 3.0 hours Kirk Smith 4.0 hours Robert V. Tauxe, M.D., MPH 2.0 hours Dr. Fred C. Tenover 1.0 hours Nathan M. Thielman, M.D., MPH 2.0 hours RADM Linda Tollefson, DVM, MPH 3.0 hours Curtis Travis, Ph.D. 2.0 hours David J. Vose 3.0 hours Robert D. Walker, M.S., Ph.D. 2.0 hours Henrik C. Wegener, Ph.D., M.Sc. 2.0 hours David G. White, M.S., Ph.D. 1.0 hours Christopher A. Ohl, M.D. 2.0 hours

Respectfully submitted,

Robert B. Nicholas James H. Sneed Gregory A. Krauss M. Miller Baker McDERMOTT, WILL & EMERY 600 Thirteenth Street, N.W. Washington, D.C. 20005 (202) 756-8000 Counsel for Bayer

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of Bayer's Request for Cross-Examination was hand-delivered this 14th day of April, 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 foregoing Request for Cross-Examination was emailed this 14th day of April 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 foregoing Request for Cross-Examination was emailed and mailed via first-class mail, postage pre-paid, 14th day of April 2003 to:

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

Kent D. McClure Animal Health Institute 1325 G Street, N.W, Suite 700 Washington, D.C. 20005

Robert B. Nicholas Counsel for Bayer