



AMERICAN ASSOCIATION FOR LABORATORY ANIMAL SCIENCE

AALAS advances responsible laboratory animal care and use to benefit people and animals

9190 Crestwyn Hills Dr
Memphis, TN 38125-8538
(901) 754-8620
fax (901) 753-0046
e-mail info@aalas.org

February 7, 2003

Food and Drug Administration
5630 Fishers Lanes, Room 1061
Rockville, MD 20852

RE: Docket Number 02N-0452
Dockets Management Branch (HFB-305)

Dear Sir or Madam:

The American Association for Laboratory Animal Science (AALAS) is pleased to have the opportunity to provide comment to the Food and Drug Administration regarding Docket 02N-0452 Comment Request: New Drug and Biological Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible. AALAS is an organization of laboratory animal scientists whose mission is to advance responsible care and use of laboratory animals to benefit people and animals. Therefore, AALAS is the premier forum for the exchange of information and expertise in the care and use of laboratory animals. AALAS membership consists of more than 11,000 clinical veterinarians, technicians, technologists, educators, and business people, researchers, administrators, animal producers and national and international experts. AALAS plays a leadership role in helping to facilitate biomedical research through training, scientific programs, and advocacy roles whenever laboratory animals are used in research, teaching, and testing.

AALAS strongly supports the use of laboratory animals in biomedical research to discover and develop new drugs and biological products that benefit both humans and animals, provided the work is performed in a responsible and humane manner.

We encourage the FDA to support research studies that are conducted in full compliance with all applicable federal, state and local regulations. We promote work utilizing sound experimental design in scientifically controlled studies to minimize the number of laboratory animals used, yet with adequate statistical power and precision. Such studies are conducive to valid conclusions in the discovery and development of efficacious and safe drugs and biologicals.

- EXECUTIVE COMMITTEE**
- President**
Cynthia A. Pokow, DVM
VA Project Scientist Health Care Services
Scott, WA
 - Vice President**
Gail A. Heitlerink, RVMG
Boehringer-Ingelheim
Whitefish, WI
 - Vice President-Elect**
V. Hugh Price, DVM
FBI Wildlife Services Center
Shirlington, VA
 - Past President**
Craig S. Frisk, DVM, PhD
MVA Foundation
Rockledge, MN
 - Secretary/Treasurer**
Jack R. Flossler, DVM
Columbus, OH
 - Attorney at Law**
Thomas H. Boersingher
MCA Animal Associates
Chico, IL
- TRUSTEES**
- District One**
Stanley P. Lieberberg, DVM
Central West Virginia
Martinsburg, WV
 - Kathleen T. Smoler, DVM
Vet Health Services, Inc.
Chico, GA
 - District Two**
Ann Marie Dunkel, BS, RVMG
Dunn Veterinary Laboratories, Inc.
Troy, MI
 - Leopold M. Yamas, RVMG
Netherlands
Summit, NJ
 - District Three**
Doreen H. Bartlett, BS, VMD
School of Veterinary Medicine
Gainesville, TX
 - Judith T. Snow, MBA, VMD
BIOGEN, Inc.
Cockeysville, MD
 - District Four**
Margaret C. Hogan, RVMG
D.J. Evans, Inc.
Johannesburg, GA
 - Darrell F. Hoskins, DVM
Scripps Institution of Oceanography
La Jolla, CA
 - District Five**
Richard S. Clark, BS, RVMG
Boehringer-Ingelheim
East Orange, NJ
 - Kim Longnecker, RVMG
Olin Veterinary Services
Cedar Rapids, IA
 - District Six**
James Michael Byrne, DVMG
MCA Foundation
Rockledge, MN
 - Rita E. Moore, DVMG
VSDA, MSW
Mills, IA
 - District Seven**
Valen Lamstorf, RVMG
Lifestock Management, Inc.
Muncie, IN
 - Leola H. McGalloway, MVM
Watershed Veterinary Services
Baltimore, VA
 - District Eight**
James J. Baer, DVM, MS
FBI Wildlife Services Center
Shirlington, VA
 - Ardis K. Roseberry, BS
A.K. Roseberry Associates
San Francisco, CA
- EXECUTIVE DIRECTOR**
Ann Tourigny Turner, PhD, CVT


02 N-0452

CI

We encourage the FDA to support research that has strongly considered the use of scientifically valid alternatives to animal use in an effort to either reduce, refine, or replace animal models. In addition, we request you support animal studies where animals are cared for and used under the standards for animal care and use as outlined in the 1996 Institute for Laboratory Animal Research (ILAR), National Academy of Science publication *Guide for the Care and Use of Laboratory Animals*.

For further information about AALAS and our policy regarding animal care and use, you are encouraged to visit our website at www.aalas.org or you may contact us directly for more information.

Sincerely yours,



Cynthia A. Pekow, DVM
President, AALAS