February 22, 2011

Divisions of Document Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-N-0548 Advance Notice of Proposed Rulemaking
Good Laboratory Practice for Nonclinical Laboratory Studies

Dear Sir/Madam:

This letter is in response to the Food and Drug Administration’s solicitation of comments regarding whether to amend the regulations governing Good Laboratory Practices (GLPs) and how to receive documentation of compliance with existing statutory provisions or comparable international standards governing the ethical and humane use of laboratory animals in nonclinical laboratory studies.

The National Association for Biomedical Research (NABR) represents more than 300 public and private universities, medical and veterinary schools, teaching hospitals, voluntary health organizations, professional societies, pharmaceutical and biotech companies regarding sound public policy on the humane use of animals in biomedical research and safety testing. NABR’s comments specifically address the following as published in Federal Register 75:244 (December 21, 2010) p. 80011.

5. Animal Welfare. In the United States, the Animal Welfare Act (7 U.S.C 2131-2159) governs the treatment and use of animals, including their use for research purposes. FDA is soliciting comments regarding whether and how to receive documentation of compliance with these existing statutory provisions or comparable international standards governing the ethical and humane use of laboratory animals in nonclinical laboratory studies. This issue is not specifically addressed in the present regulation.

Consistent with the President’s Executive Order dated January 18, 2011 titled “Improving Regulation and Regulatory Review - Executive Order” NABR believes the creation of new FDA animal welfare regulations would be duplicative and unnecessary. The United States Department of Agriculture (USDA), the federal regulatory agency charged with enforcing the federal Animal Welfare Act (AWA) currently performs unannounced inspections of research facilities at least annually and generates publicly available inspection reports. Institutional Animal Care and Use Committees (IACUCs), independent bodies required by the AWA, also monitor animal welfare based on USDA regulations and on the Guide for the Care and Use of Laboratory Animals (National Academies of Science 1996). IACUCs review and approve proposed animal use (protocols), inspect facilities, and oversee the institution’s animal care and use.
program. Documentation of IACUC activities is readily available in the form of inspection reports, meeting minutes and protocol files. In addition, most GLP-compliant facilities are voluntarily accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. Proof of accreditation in the form of formal letters from AAALAC is also available. FDA is currently able to determine animal welfare compliance by reviewing available USDA inspection reports, by reviewing existing IACUC documentation, by verifying AAALAC accreditation status, and by the direct observation of animals during FDA inspections.

Moreover, a longstanding Memorandum of Understanding (MOU) exists between the USDA, FDA and the National Institutes of Health (NIH). The current MOU dated March 1, 2006 states the agencies “…share a common concern for the care and use of laboratory animals, although there are necessary operational differences among the animal welfare programs of the cooperating agencies. Congress acknowledged the need for transagency cooperation in the AWA by calling for the Secretary of Agriculture to consult and cooperate with other Federal departments and agencies concerned with the welfare of animals used in research, and to consult with the Secretary of Health and Human Services prior to the issuance of regulations." The agencies therefore agreed “to consult and coordinate with each other on regulatory or policy proposals and significant policy interpretations involving animal care and use under consideration by each agency.” As agreed to in the MOU, NABR urges the FDA to continue working closely with the USDA and NIH with respect to the care and use of animals in research rather than create unnecessary new regulations.

Since multiple animal welfare requirements already govern research facilities depending on their specific work (e.g. USDA’s Animal Welfare Regulations, the Guide for the Care and Use of Laboratory Animals, the European Convention for Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (ETS No. 123), etc.), creating additional rules would be redundant and potentially conflicting and/or confusing. FDA’s efforts would be best focused on assuring that proper documentation is in place and allowing the federal regulatory agency responsible for the applicable statute or standard to determine whether the facility is in compliance.

Sincerely,

Frankie L. Trull
President