

FASEB Comments on the USDA Animal Care Policy

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the United States Department of Agriculture (USDA) Animal Care Policy Manual, as solicited by the announcement that appeared at <http://www.aphis.usda.gov/guidance/>. FASEB is a coalition of 21 life science societies representing more than 80,000 biomedical researchers, many of whom are involved in the humane use of animal models in research and education.

It is critically important that local Institutional Animal Care and Use Committees (IACUCs) be given clear and unambiguous direction for ensuring compliance with existing statutory and regulatory requirements. Therefore, FASEB joins with our colleagues at the National Association for Biomedical Research (NABR) in calling for clarifying language in accordance with the requirements of the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" published in the *Federal Register* on January 25, 2007 (72 FR 3432–3440), which can be found at http://www.whitehouse.gov/omb/fedreg/2007/012507_good_guidance.pdf. Specifically, we recommend the following be applied to all guidance documents which collectively comprise the USDA Animal Care Policy Manual:

Compliance with OMB guidance: Each existing Policy should be reviewed in accordance with Section II, h of the OMB's "Final Bulletin for Agency Good Guidance Practices" to eliminate any use of "mandatory language such as 'shall,' 'must,' 'required' or 'requirement,' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties." In making these revisions the language should indicate that alternatives for complying with the suggested course of action are permissible.

Preface and header language: The Animal Care Policy Manual should include a Preface containing language modeled after that used by the Food and Drug Administration (FDA) in its Compliance Policy Guide. Specifically we recommend the following language be included in that Preface, "This guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind USDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations." In addition each Policy document should include the following language, "USDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited." Moreover, consistent with current practice at the FDA, each page of the Animal Care Policy Manual should contain the following header, "CONTAINS NON-BINDING RECOMMENDATIONS."

Again, FASEB thanks you for this opportunity to provide feedback. If you have questions or need additional information, please do not hesitate to contact us.

Sincerely,

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FASEB President