November 12, 2007

USDA/APHIS/AC
4700 River Road, Unit 84
Riverdale, MD 20737-1234

Re: Docket ID: APHIS-2007-0110

This review was conducted in response to the announcement that appeared at http://www.aphis.usda.gov/guidance/ 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. The following comments include general recommendations, which should apply to all guidance documents contained within what is currently called the Animal Care Policy Manual and specific comments that refer to the Policies contained within that Manual.

General Recommendations:

1. The Animal Care Policy Manual should include a Preface containing language similar to that used by the Food and Drug Administration (FDA) in its Compliance Policy Guide, which can be found at http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg130-300.html. 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.”

2. Consistent with current practice at the FDA, each page of the Animal Care Policy Manual should contain the following header, “CONTAINS NON-BINDING RECOMMENDATIONS.”
3. Each existing Policy should be reviewed in accordance with Section II, h of the OMB’s Final Bulletin for Agency Good Guidance 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.

Specific Comments:

Policy 1 - Denial of AWA License Applications – The language in the current Justification section needs to be revised to read, “This policy guidance document serves to clarify when a license application can be denied, and when and what it means for a license to be invalid.”

Policy 2 - Submission of Traveling Exhibitor Itinerary – The language in the current History section needs to be revised to read, “This is a new policy statement revised guidance document, to remain in effect until enacted into regulatory changes. It is not binding on regulated entities and the Agency will consider alternate positions advanced by affected private parties.” Since this policy was initially issued on April 17, 1997 and was to remain in effect until regulatory changes are implemented, it would seem that the appropriate regulatory changes should be enacted to eliminate this Policy.

Policy 3 – Veterinary Care – This Policy contains sections on Expired Medical Materials, Pharmaceutical-Grade Compounds in Research, Surgery, Pre- and Post- Procedural Care, Program of Veterinary Care, Declawing and Defanging Practices in Wild or Exotic Carnivores or Nonhuman Primates, Health Records and Euthanasia.

Pharmaceutical-Grade Compounds in Research – The current use of the phrases “pharmaceutical-grade medications” and “pharmaceutical-grade compounds” has created some confusion for those serving on IACUCs. We would suggest the wording be changed to read “pharmaceutical-grade compounds used as medications.”

Surgery – The first paragraph of this section contains the following statement, “Research facilities doing surgical demonstrations while traveling must use aseptic techniques and dedicated surgical facilities.” If the surgical demonstrations being done are non-survival procedures, the current language exceeds the requirements contained in the regulations and should be removed from the Policy and made consistent with the regulations.

Pre- and Post-procedural Care - The first paragraph of this section contains the following statement, “However, the attending veterinarian retains the authority to change post-operative care as necessary to ensure the comfort of the animal.” It would eliminate potential confusion if this section clarified that IACUC approval is not required when the
attending veterinarian makes adjustments in post-operative care as necessary to ensure the comfort of the animals. The final sentence in the second paragraph needs to be revised to be consistent with Sections 15.5.2 of the Research Facility Inspection Guide.

**Health Records** – This entire section needs to be revised to be consistent with Sections 14.3.1 & 15.3.1 of the Research Facility Inspection Guide.

**Policy 5 – Licensing of Exotic Animal Auction Markets** - Since this Policy was initially issued on April 17, 1997 and remains in effect until proposed regulations are cleared and published, it would seem that appropriate regulatory changes should be enacted to eliminate this Policy.

**Policy 6 – Space and Exercise Requirements for Traveling Exhibitors** - The following language is contained in the History section, “It expands and clarifies enclosure space and exercise requirements for traveling exhibitors.” The use of the word “expands” when referring to enclosure space implies that the Policy exceeds the language in the regulatory standards.

**Policy 11 – Painful Procedure** – The definition of a painful procedure incorporated in this Policy is not the same as the definition contained in Part 1 of Subchapter A, which contains the following modifying clause “…that is pain in excess of that caused by injections or other minor procedures.” The definition in the Policy should be identical to the one contained in Part 1 Subchapter A, because the entire definition is essential for the IACUC to define when a procedure is likely to cause more pain than incurred by utilizing an injection or other minor procedure to administer an appropriate anesthetic or analgesic agent and thus eliminate the expectation for more than momentary pain or distress. As currently written, Policy 11 creates unnecessary ambiguity and has been interpreted by some inspectors and IACUCs as requiring investigators to provide written narrative descriptions of their consideration of alternatives to potentially painful procedures even though the procedures do not meet the definition of a painful procedure contained in Part 1. A common example of this would be proposed projects that utilize non-survival/acute surgical procedures. Using the definition contained in Subchapter A, there would be no reasonable expectation for the animals to experience pain in excess of that caused by an injection and thus would not require the investigator to do a search for alternatives. The same could be said for the use of Freund’s Adjuvant when appropriate anesthetics and/or analgesics are used.

The last paragraph of this Policy specifies requirements for the Annual Report. These requirements should be removed from this Policy since it creates the impression the same criteria used to determine whether a procedure should be reported in Column D of the Annual Report is being used to define a potentially painful procedure for the purposes of a protocol review.

**Policy 12 – Consideration of Alternatives to Painful/Distressful Procedures** – While this Policy describes alternatives or alternative methods in terms of the 3 R’s (Replacement, Reduction and Refinement), it does not provide guidance on what to do when they are actually used. This would be relatively easy to do in terms of Reduction
and Refinement. For example if a proposal includes a power analysis that determines the least number of animals possible to produce the desired result then not only has an alternative been considered, but it has been utilized and additional justification should not be required. The same holds true for Refinement where the use of the latest means of managing potential pain and distress as recommended by the veterinarian would constitute not only a consideration of but an actual use of alternative methodologies.

Policy 14 – Major Survival Procedures vs. Multiple Procedures - As written this Policy appears to prohibit the use of animals in more than one proposal involving a major operative procedure. Such a prohibition or limitation exceeds the authority provided in the AWA and the regulations. Therefore, this guidance document needs to be revised to be consistent with existing statutory and regulatory authority. Both the Act and the regulations require that such usage be scientifically justified, but there is no requirement for limiting that use to one proposed activity. In addition the word “emergency” has been inserted before the phrase “veterinary care provisions”. The regulations (2.31 Institutional Animal Care and Use Committee (IACUC)) use the phrase, “routine veterinary procedure.” The language in the Policy should be consistent with the language in the regulations.

The Policy also sets forth a process for obtaining an exemption to limitations created by the Policy. The Policy then goes on to state that “The exemption must be included in the Annual Report (APHIS 7023).” The regulations (2.36 Annual Report) refer to the reporting of exceptions. Since an exception is defined by Merriam-Webster Online Dictionary as “a case to which a rule does not apply,” an exemption granted based upon specific language in the regulations is by definition not an exception and is not required to be included in the Annual Report. The final sentence needs to be deleted to be consistent with the rationale provided above.

Policy – 16 – Dealers Selling Surgically-Altered Animals to Research – The third sentence in the second paragraph of the Policy section needs to be revised to read, “If the alteration involves a major operative procedure, the animal should be identified to either prevent its use in another major survival operative procedure or to assure that the alteration is included in a proposal requiring scientifically justified multiple procedures.”

Policy – 17 Annual Report – The Animal Welfare Act requires that the Annual Report contain information on procedures likely to produce pain and distress. Congress intended for registrants to report animals identified during a prospective assessment of the proposed activities. The language contained in this Policy requires that the animal usage information shall be correct and complete and involve the use of an accounting method sufficient to support the numbers reported. This language raises the issue of the accuracy that can be documented from prospective assessments. In addition this Policy requires that the Annual Report include exemptions to the dog exercise plan and/or the nonhuman primate plan for environmental enrichment. Since both Sections 3.8 and 3.81 provide a mechanism for granting exemptions, requiring such exemptions to be included in the annual report as exceptions (“a case to which a rule does not apply,”) exceeds the
authority of the statute and the regulations. This requirement should therefore be removed from this Policy to be consistent with the statute and the regulations.

Policy 18- Health Certificate for Dog, Cats and Nonhuman Primates – While this policy appropriately clarifies the requirement for a health certificate contained within the regulations, it should be noted that the 10 day time limit allowed in the process does not provide assurance that an animal will be free of an infectious disease that would endanger other animals or present a public health risk at the time of transport.

Policy 19 – Tattoo Identification of Dogs and Cats – The Justification section of this Policy should indicate that this is a guidance document

Policy 21- Control of Tuberculosis in Regulated Elephants – The History section of this Policy should indicate that this is a guidance document. The first paragraph contains language that appears to only require animals be quarantined when they are culture positive. Given the difficulty often encountered in culturing these organisms, should not the guidance be to quarantine those animals that test positive? In the last paragraph of the Policy the agency is requiring annual testing of staff for tuberculosis. It is questionable whether, and unclear as to which sections of the regulations authorize this requirement.

Policy 22 – Necropsy Requirements – The History section of this Policy should indicate that this is a guidance document, which is not binding on regulated entities and the Agency will consider alternate positions advanced by affected private parties.

Policy 23 – Criteria for Licensing Hoofstock Dealers - The criteria used in this Policy to determine which individuals need to be licensed does not appear to be consistent with the requirements in Section 2.1 (a)(3)(i) & (ii) of the Regulations.

Policy 25 – Proper Diets for Large Felids - The History section of this Policy should indicate that this is a guidance document.

Policy 26 – Regulation of Agricultural Animals - The History section of this Policy should indicate that this is a guidance document.

Policy 28 – Licensing Sales of Dead Animals – The History section of this Policy should indicate that this is a guidance document. Given the language that appears in the Animal Welfare Act, the examples used in this Policy for when a license is not required do not seem to be consistent with the statutory language.

Sincerely,

Mary F. Hanley
Executive Vice President