

Supporting Statement
Animal Welfare, Subparts A, D, E, and F
OMB #0579-0093

Introduction

September 2006

Collection 0115, Animal Welfare, Marine Mammals is being consolidated with this collection, 0093, as part of this renewal package. These two collections include the same regulations and the same forms; therefore, it will be more efficient to have them consolidated into one collection.

When the collections were combined and figures adjusted, burden figures went from 34,918 to 47,591. See question 15 for more details.

Justification:

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The Laboratory Animal Welfare Act (AWA) (Public Law 89-544) enacted August 24, 1966, and amended December 24, 1970 (Public Law 91-579); April 22, 1976 (Public Law 94-279); and December 23, 1985 (Public Law 99-198) requires the U.S. Department of Agriculture (USDA) to regulate the humane care and handling of most warm-blooded animals, including marine mammals, used for research or exhibition purposes, sold as pets, or transported in commerce. This legislation and its amendments were the result of extensive demand by organized animal welfare groups and private citizens requesting a Federal law to protect such animals. USDA, Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) has the responsibility to enforce the AWA and the provisions of 9 CFR, Chapter 1, Subchapter A, which implements the AWA.

The stated purpose of the AWA, Section 1(b), includes the following:

- (1) to ensure that animals intended for use in research facilities or exhibition purposes or for use as pets are provided humane care and treatment;
- (2) to ensure the humane treatment of animals during transportation in commerce; and
- (3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen..."

Section 21 of the Act authorizes the Secretary to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of the Act.

Sections 10, 11, 12, and 13 of the AWA authorize and require certain record keeping requirements for regulated facilities. Title 9 CFR Subchapter A, Part 3 stipulates certain conditions that must be documented in order for dealers, exhibitors, research facilities, etc. to hold, buy, sell, and/or ship animals. Records of these conditions and their use must be kept for a

period of at least one year. These records are necessary for APHIS to review to ensure that the animals are cared for in the prescribed manner that is required by the regulations.

Part 3 of Subchapter A addresses the specifications for humane handling, care, treatment, and transportation of regulated animals, including areas such as facilities construction, veterinary care, personnel, feeding, water quality, sanitation, space requirements, transportation enclosures, and handling and care in transit. Subpart A addresses the specifications for dogs and cats, Subpart B for guinea pigs and hamsters, Subpart C for rabbits, Subpart D for nonhuman primates, Subpart E for marine mammals, and Subpart F for all other regulated animals.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS has the regulatory authority to enforce the AWA. APHIS also prepares an annual report and other documents that pertain to animal welfare activities. Information for these documents depends on the proper recording and reporting of the information received in the above mentioned records. APHIS must be equipped with data on research facilities in order to make a professional assessment of animal conditions. Not providing this data would be contrary to the intent of the Act and would prevent prosecution of violators.

Furthermore, the records and reports herein provide APHIS with the data necessary for the review and evaluation of program compliance by regulated facilities. This recorded information becomes a part of the enforcement system that carries out the requirements of the Act and the intent of Congress. This is accomplished on a practical daily basis without the use of more detailed and stringent regulations and standards that could be more burdensome to regulated facilities.

Section 3.6(b)(1)(iii), 3.6(c)(1)(ii), 3.6(d): There are additional space requirements for dogs and/or cats with litters of young. If the additional space provided for each offspring is less than 5 percent of minimum required for the dam, the lesser space must be approved by the attending veterinarian and, if the animals are being used in an active protocol, the Institutional Animal Care and Use Committee (IACUC) of a research facility. In the case of a dealer, the lesser space must be approved by the Administrator. These requirements are to ensure that the dogs and cats are afforded the required space to ensure that the animals are comfortable in accordance with good husbandry practices. The applicable sections are 3.6(b)(1)(iii) for cats, and 3.6(c)(1)(ii) for dogs.

Innovative primary enclosures that do not precisely meet the floor requirements for space will be allowed in research facilities when approved by the IACUC, and in dealer premises when approved by the Administrator only if there is sufficient space and the opportunity to express species-typical behavior.

Records of the approval must be maintained and are subject to APHIS' inspection.

Section 3.8, 3.8b(1)(2)(3), 3.8(c)(1), 3.8(c)(3)(iii), 3.8(d)(1)(2)(3): Exercise and socialization for dogs. The 1985 amendments to the Act require the Secretary to promulgate standards for "...exercise of dogs as determined by an attending veterinarian in accordance with general

standards promulgated by the Secretary...” Research facilities, dealers, and some exhibitors will be required to maintain written standard procedures for the exercise of dogs. The attending veterinarian is authorized to exempt certain animals from the exercise requirements based on the animal’s needs or research requirements. The IACUC must also approve the exemption during its review process. Any such exceptions must be recorded and reviewed periodically by the attending veterinarian and the IACUC.

The written standard procedures will be maintained by the facility and reviewed by APHIS’ inspectors during inspections to assure the intent of the Act is followed. The plan must be in accordance with professionally accepted standards as directed by the attending veterinarian.

Sections 3.13(b), 3.13(c), 3.13(e), 3.14(h), 3.16(a), 3.16(b), 3.19(a), 3.35(b), 3.35(c), 3.36(h), 3.37(g), 3.60(b), 3.60(c), 3.61(g), 3.62(g), 3.77(a), 3.78(a), 3.86(b), 3.86(c), 3.89(a), 3.89(b),), 3.92(a), 3.112(b), 3.112(c), 3.113(g), 3.118 (a), 3.136(b), 3.86(c), 3.137(f), 3.139(d):

Consignments to carriers and intermediate handlers. Certain information, instructions, and certifications are required for the humane transportation of animals in commerce. The consignor must provide: current name and address, official identification of animals being shipped to carriers and intermediate handlers; food and water certification and instructions for each shipment. Some certifications are mandatory (food and water) for some animals, and some are optional (enclosure requirements and acclimation to temperature). Shipping documents must be affixed to the transport enclosure or be carried by the attendant.

The optional certifications, such as acclimation to lower temperatures and certification that the transport cage complies with standards, are not mandatory; however, this certification may make it possible for the handlers to accept shipments that they would otherwise refuse. For example, airlines will not normally accept animals for transport in very cold weather. However, if the consignor’s veterinarian certifies that the animals are acclimated to cold temperatures, then the airline may accept the shipment which they would otherwise refuse. This provides a system for certain animals to be shipped if there is no threat of harm to them rather than applying a blanket prohibition on such movements.

This information and certification are necessary for carriers and intermediate handlers to properly care for and deliver the animals to designation in speedy and humane manner. APHIS’ inspectors at airports and shipping points also use these documents to reference instances of violations for possible legal action, locate facilities or persons who are evading regulation under the law, or other actions necessary for the enforcement of the Act.

Section 3.13(f), 3.35(d), 3.60(d), 3.86(f), 3.112(d), 3.136(d): Carriers are required to attempt to notify consignee of arrival of a shipment of animals within 6 hours of arrival and at least each following 6 hours until the animals are claimed by the consignee or returned to the consignor. This requirement is designed to ensure that the animals are delivered in a timely fashion. Records must be kept to ensure APHIS’ inspectors that the consignee was either contacted or the attempts were made to notify the party.

Section 3.14(a)(6), 3.19(b)(2), 3.36(g), 3.61(f), 3.87(f), 3.92(b)(2), 3.113(f), 3.137(e):

Markings identifying shipping crates to be holding live animals and directional arrows identifying the upright direction for the kennel are required on the crates when being shipped. These markings are required to identify kennels readily, therefore ensuring the proper handling and the safety of animals being shipped.

Section 3.77(f), 3.78(d), 3.127(d): The outdoor areas of a sheltered housing facility or outdoor housing facility must be enclosed by a fence that is of sufficient height to keep unwanted species out. Fences less than 6 feet high must be approved by the Administrator of APHIS. Potentially dangerous species require an 8 foot perimeter fence. Alternate safety protocols may be used with the approval of the Administrator. Requests for approval of alternative security measure that meet or exceed the safety provided to the animals and the public in the regulations concerning perimeter fences for marine mammals and animals other than cats, dogs, guinea pigs, hamsters, rabbits, nonhuman primates, and marine mammals, must be submitted to APHIS for approval. These written requests are used to evaluate the extent to which the proposed deviation from the requirements protects the animals and the public and meets the intent of the regulations. If the plan meets or exceeds the current requirements, approval is granted. This process allows for flexibility in enforcing the regulations without compromising the health and safety of the animals and the safety of the public.

Section 3.28(c)(3), 3.53(c)(3), 3.80(b)(2): Innovative primary enclosures not precisely meeting the floor area and height requirements for these species (hamster, guinea pigs, rabbits, and nonhuman primates) may be used at a research facility when approved by the IACUC, or by dealers and exhibitors when approved by the Administrator. For nonhuman primates, such enclosures that may provide environment enrichment or promote socialization may in part satisfy the requirement of the 1985 amendments to the Act that require the Secretary to promulgate standards "...for a physical environment adequate to promote the psychological well-being of primates". Documentation is necessary in order to properly enforce the law and to keep from putting unnecessary burdens on regulated facilities that may utilize innovative enclosures to satisfy other requirements of this subchapter. These documents will be subject to APHIS' inspection.

Section 3.80(c), 3.83: Any exemptions from the specifications for primary enclosures/watering requirements must be required by a research proposal or the judgment of the attending veterinarian and be approved by the IACUC or the Administrator. This will help to assure that the intent of the Act has been met.

Section 3.81, 3.81(d), 3.81(e)(1)(2)(3): Environment enhancement plan. The 1985 amendments to the Act require the Secretary to promulgate standards, "...for a physical environment adequate to promote the psychological well-being of primates". Each facility housing nonhuman primates must develop, document, and follow a plan that must address social grouping, environment enhancement, and primates or groups of primates that have special needs. The attending veterinarian or the IACUC is authorized to exempt certain animals from the plan based on the animals' needs or research requirements. Any such exceptions must be recorded and reviewed periodically by the attending veterinarian or the IACUC. The plan will be maintained by the facility and reviewed by APHIS' inspectors during inspection to assure that the intent of the Act is followed. The plan must be in accordance with professionally accepted standards as directed by the attending veterinarian. Restraint devices must be used only in necessary instances for health reasons or research protocol. When continuous restraint is to be for more than 12 hours, it must be approved by the IACUC committee in the research proposal.

Section 3.100(g): A research facility may be granted a variance for other sections of this subpart if necessary for research purposes, is explained fully in the experimental design, and is for research protocols approved by the IACUC and permitted under the MMPA.

Section 3.101(a)(3): Facilities, general. A written protocol for the cleaning of primary enclosure surfaces so that they do not constitute a health hazard to the animal(s) must be developed and maintained at the regulated facility. This plan will include cleaning, and where appropriate, disinfecting schedules and methods. These protocols are kept on site at the facility and are to be made available for APHIS inspection. These protocols need only be developed once or as needed for changing enclosures.

Section 3.101(b): Contingency plans. Written contingency plans are required to outline protocols in the event of a power failure (water and power) and in the event of an emergency, such as a natural disaster, that would require evacuation of the animals, including release into the wild and how to regain their custody. These plans must be available for APHIS inspectors to review. In general, they would only need to be changed if there was a change in back-up power systems or changes in animals/enclosures affected.

Section 3.104(a)(1): General space requirements. All animals must be maintained in enclosures which meet or exceed space requirements as set forth in this section. However, temporary holding of animals in smaller enclosures for the purposes of nonmedical training, breeding, holding or transfer is allowable if such confinement is justified in writing by the attending veterinarian on a weekly basis. These recordkeeping requirements are consistent with those of Section 3.110(b) for medical treatment and holding of marine mammals for medical training. These records are to be kept in the animal's individual medical record. This information is also used in documenting instances of violations for possible legal action.

Section 3.105(c): Feeding. Feeding records for all marine mammals, noting individual daily food consumption, must be maintained at the facility for one year and be made available for APHIS inspection. Additionally, the attending veterinarian must be notified immediately if any animal shows impedance (decrease or lack of appetite) for more than 24 hours. This information allows documentation of appropriate feeding for all marine mammals and documentation of notification of the attending veterinarian for animals which may require veterinary care. This information is also used in documenting instances of violations for possible legal action.

Section 3.106(b): Weekly and daily water testing for marine mammals. Bacterial water quality testing must be done every week, and those results must be recorded and made available to the APHIS inspector. Chemical additives and pH must be tested daily. This information is used to document instances of violations for possible legal action.

Section 3.108(b): Employees or attendants. Each marine mammal facility must document the participation and successful completion of a facility training course for each employee. Such a course is necessary, among other things, to comply with the requirement to provide adequately trained personnel. This information is also used in documenting instances of violations for possible legal action.

Section 3.109: Separation. Marine mammals known to be social in the wild are required to be housed with at least one compatible animal of the same or related species. However, if this cannot be done, any singly housed marine mammal must have a written plan, approved by the attending veterinarian, developed in conjunction with the husbandry and training staff(s), which justifies these arrangements, as well as addresses the length of time the animal is expected to be housed alone, the type and frequency of enrichment provided, appropriate interactions, and

periodic review by the attending veterinarian. This plan will be reviewed by APHIS inspectors to assure that all singly housed marine mammals are receiving appropriate care and not being subjected to unwarranted isolation. This information is also used in documenting instances of violations for possible legal action.

Section 3.110(b): Veterinary care. Animals cannot be held for the purpose of medical treatment and/or medical training for periods of time in excess of 2 weeks in medical or other enclosures which do not meet the space requirements of Section 3.104 without written justification by the attending veterinarian in the animal's medical record. These records will be inspected by APHIS to assure that no animals are being kept for medical reasons in primary enclosures which do not meet AWA requirements unless deemed medically necessary by the attending veterinarian. This information is also used in documenting instances of violations for possible legal action.

Section 3.110(d), 3.111(f) (2): Veterinary care. Individual animal records must be maintained at the facility for all marine mammals and be made available for APHIS inspection. These records must at least contain animal identification information, examination results, diagnostic tests and results, and documentation of all treatments. This information is necessary for APHIS enforcement of the requirements for providing adequate veterinary care for regulated animals (Section 2.40). This information is also used in documenting instances of violations for possible legal action.

Section 3.110(e): Veterinary care. Copies of the animal's medical record must accompany the animal when transferred to another facility. This requirement will facilitate the continuation of adequate veterinary care of the marine mammal by making sure the receiving party has a complete medical history.

Section 3.110(f): Veterinary care. All cetaceans and sirenians must be examined by the attending veterinarian 6annually unless exempted by APHIS (when in the best interest of the animal). The facility would need to request such an exemption and submit it to APHIS. This documentation would allow for all animals that can be physically evaluated (provide adequate veterinary care) to do so, and verify why a given animal cannot.

Section 3.110(g): Veterinary care. A complete necropsy on any marine mammal which dies in captivity must be conducted by or under the direct supervision of the attending veterinarian, and a preliminary and final report must be written. The report must include a listing of all results of the gross necropsy (preliminary report) and histopathological and special testing (final report). This report must be maintained on site for a period of 3 years, and made available to APHIS inspectors upon request. Reporting of necropsy results and maintenance of these records for inspection is necessary to allow APHIS to evaluate veterinary care under the AWA. Retention of records for three years allows evaluation of disease, handling, or husbandry trends in marine mammal deaths at the facility. This information is also used in documenting instances of violations for possible legal action.

Section 3.111(e) (4): Handling. Written rules and instructions must be supplied to members of the public participating in SWTD programs. The participants must agree, in writing, to abide by the rules and instructions of the attendants. The interactive nature of the SWTD programs provides a risk of injury to the animals and the public. Rules to safeguard the dolphins must be adhered to prevent undue risk to the health and well-being of the dolphins. Providing written

instructions and obtaining written agreement from the human participants is necessary to maintain and enforce these safeguards.

Section 3.111(e) (7): Handling. Written criteria for the conditions and procedures for termination of a SWTD session where unsatisfactory human/dolphin interactive behaviors are exhibited must be submitted to APHIS. Such written criteria are needed to provide consistent and adequate safeguards when a facility is faced with interactions deemed unsatisfactory and/or dangerous to the health and well-being of the marine mammal or member of the public. This information is also used in documenting instances of violations for possible legal action.

Section 3.111(f) (1): Recordkeeping. A description of the SWTD program, including identification of all animals in the program, description of the educational content of the program, the agenda for the interactive session, method and content of pre-encounter orientation and rules, facility description, animal training procedures used prior to participation in the program, a resume of all staff involved with the dolphins, assessment of current animal behavior patterns by the attending veterinarian, a written program of veterinary care (APHIS form 7002) if the attending veterinarian is part-time or a consultant, and a description of the animal behavior monitoring program which will be used to assess behavioral changes in program animals, must be submitted to APHIS.

The use of APHIS form 7002 has been addressed in previous OMB review of Parts 1 and 2 of the AWA regulations. The use of written rules and orientation materials is addressed under Section 3.111(e) (4). Facilities descriptions are necessary to evaluate compliance with the space requirements listed in Section 3.111(a). Submission of a resume for employees is necessary to evaluate compliance with the regulations covering employees and attendants in Section 3.111(c). Animal identification information is necessary to evaluate compliance with program animal requirements in Section 3.111(d). Training procedures and animal behavior monitoring are necessary to evaluate compliance with handling requirements in 3.111(e) (2).

The nature of SWTDs, the unique risks associated with interactive programs, and the unavailability of any long term evaluation of the affects of SWTD programs on marine mammals, necessitates the documentation of SWTD procedures, protocols, and safety measures. This documentation is submitted once from each facility. This information is also used in documenting instances of violations for possible legal action.

Section 3.111 (f) (3): Recordkeeping. Individual animal veterinary records must be maintained at the facility for 3 years, and made available to APHIS on request. Veterinary records are a necessary to in the evaluation for adequate veterinary care. Retaining records for 3 years for the SWTD programs is necessary to monitor the potential effects of the interactive program on the long term health and well-being of the animals. This information is also used in documenting instances of violations for possible legal action.

Section 3.111(g) (6): Necropsy reporting and recordkeeping requirements and justification are addressed in Section 3.110(d). Section 3.111(g) (6) includes regulation of post-mortem handling of the animal and requirement that the necropsy be performed by a veterinarian experienced in marine mammal necropsies. This does not increase any recordkeeping or reporting burden. The record maintenance requirement of 3 years found in Section 3.110(d) applies to Swim-with-the-dolphin (SWTD) programs as well.

Section 3.111(f) (4): Recordkeeping. Individual animal feeding and behavioral records must be maintained on site for a period of at least 3 years. Due to the specialized nature of the SWTDs, evaluation of feeding and behavioral records by APHIS inspectors is necessary to assure proper handling and care under the AWA. This information is also used in documenting instances of violations for possible legal action.

Section 3.111 (f) (5): Recordkeeping. Statistical summaries of dolphin and human participation in the SWTD program must be maintained at the facility for 3 years and provided to APHIS semiannually. These summaries will be used to evaluate the interactive programs and aid in monitoring of safety of such interactive activities. The facility must also report to APHIS any changes in the SWTD program semi-annually. This information allows maintenance of accurate records on the facility and program by APHIS to be used to evaluate compliance with Section 3.111(e). This information is also used in documenting instances of violations for possible legal action.

Section 3.111(f) (6): Recordkeeping. All incidents resulting in injury to either dolphin or human must be reported to APHIS within 24 hours of the incident, and a written report of the incident must be submitted to APHIS within 7 days. Included in the written report must be a plan to prevent further occurrences of similar incidences. Interactive programs carry a risk of injury to the participants. Reporting of such incidences in a timely matter will help monitor the safety of such programs and allow appropriate intervention when indicated to prevent injury to the dolphins or people.

Section 3.111(g) (3): Veterinary Care. As part of the individual animal veterinary record, a complete physical exam will be performed every 6 months. As part of the record of this exam, an animal profile, which will include the dolphin identification, weight, length, axillary girth, appetite, and behavior, will be recorded. All other information generated through the physical exam will also be recorded. APHIS inspectors will use this information to evaluate compliance with the veterinary care requirements under the AWA, as well as monitoring acute and long-term effects of the interactive program on the health and well-being of the animal. This information is also used in documenting instances of violations for possible legal action.

Section 3.111(g) (4): Veterinary Care. The attending veterinarian will record the nutritional status and reproductive status of the animal. These records will be used to monitor the health and well-being of the program animals, used in evaluation of adequate veterinary care and feeding requirements under the AWA. This information is also used in documenting instances of violations for possible legal action.

Section 3.111(g) (5): Veterinary care. A written assessment of the water quality records will be made by the attending veterinarian during his/her monthly visit to the facility. Maintaining adequate water quality in the enclosures for SWTD programs is crucial to ensuring the health and well-being of the dolphin and human participants in the interactive sessions. The frequency of APHIS inspections does not allow for monthly monitoring of water quality records. Utilizing the attending veterinarian to assist in monitoring water quality parameters will aid in evaluation of water quality records. Water quality records are addressed in Section 3.106(b) (3). This information is also used in documenting instances of violations for possible legal action.

Section 3.112(a), 3.116(b), 3.86(e): Consignments to carriers and intermediate handlers/care in transit - health certificates. All marine mammals being transported must be accompanied by a

health certificate signed by the attending veterinarian. This provision allows for documentation that all animals being transported are in good health, or, if consistent with the conditions set forth in Section 3.116 (marine mammals), are acceptable candidates for transport. This information will be used in documenting instances of violations for possible legal action.

Section 3.116(a): Care in transit. Any transport of a marine mammal which will exceed 2 hours in duration requires that a transportation plan approved by the attending veterinarian be developed. This plan should outline the transport, identify the needs of the animal and the need to have a veterinarian in attendance or not. Such planning is necessary to assure that the animal is handled in the most humane and expeditious manner as required in Section 2.131. This information is also used in documenting instances of violations for possible legal action.

Records Retention

Records required for these sections need to be maintained and available for APHIS inspection. This usually means a minimum of 1 year. These records are structured to minimize the reporting burden for the regulated party and yet meet the provisions of the Act.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Due to the extreme differences in the operation of the various licensees and registrants, a uniform, technical reporting system is impossible. As an example, standards for the dealers' operations and the standards that the research community maintains differ widely. Also, there is a vast difference in the physical plants and the economic and administrative structures of licensees and registrants. At this time, there is not a system that would improve APHIS' methods of attaining necessary information.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

APHIS is the only Agency charged with enforcement of the AWA; therefore, there is no duplication.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information collected is the minimum required to ensure that the AWA is being enforced.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted, or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The collection of the information set forth in these sections of the regulations includes the numbers of animals on hand, categories of experimentation, identification of animals, location of premises, and the assurance by responsible officials that standards are in compliance and are vital to meeting the intent of the Act. Records must be available for AC inspectors. Without these records, investigations and proceedings against violators would be impossible. If none or only partial knowledge could be obtained from records, animal health certification would be a risk, and animals exposed to disease could not be properly accounted for or traced. The health and veterinary care and housing enforcement would be negated due to inadequate recordkeeping. APHIS must be equipped with data on research facilities in order to make a professional assessment of animal conditions. Not providing this data would be contrary to the intent of the Act and prevent prosecution of violators. The marketing of dogs, cats, and/or primates from dealers and exhibitors without supportive documentation would contribute to the violation of the standards of the Act.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

No inconsistencies with CFR 1320.5 exist, except that respondents will maintain necropsy reports for Swim-with-the-Dolphin animals for 3 years, required in Section 3.111(f) (3) Retention of necropsy records for three years for Swim-with-the-Dolphin animals are needed to assess any long term health problems which may be associated with these interactive programs. APHIS Veterinary Medical Officers routinely inspect and evaluate these records to illuminate and document any ongoing and/or emerging problems so that proper intervention and changes can be instituted.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB

Stephanie Shain
The Humane Society of the United States
201-452-1100

Ms. Kathy Liss
Animal Welfare Institute
202-337-2332

Dr. Kathryn Bayne
American Association for Accreditation of Laboratory Animal Care, International
301-231-5353

On Friday, April 28, 2006, pages 25133-25134, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. APHIS received two comments during the Notice period but it did not pertain to paperwork burden on the public. A copy of the Federal Register notice is attached.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There is no payment or gifts provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

There is no confidentiality assured except for those documents which research facilities are required to keep on file describing their animal care and use procedures. APHIS' inspectors will have access to these documents to assure compliance with the Act; however, they must maintain the confidentiality of such information and may not remove any documents from the research facility unless they are required to support the investigation of a possible violation. The provision for such confidentiality is found in Section 2.35 of 9 CFR, where the burden is cleared under OMB 0579-0036.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and others that are considered private.

There are no questions of a sensitive nature asked of the respondents.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

A total of 47,591 burden hours are needed to complete this information collection activity. The estimates were developed from historical data, calculated average number of respondents, and from discussion with field personnel. A detailed burden estimate has been included on the enclosed APHIS 71.

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information.

There is no additional cost burden to the respondents or recordkeepers.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The estimated total cost for the Federal Government is \$265,904.35. See APHIS Form 79.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

There is a difference of 12,674 total burden hours. Of this total, 2,924 is from an adjusted increase of respondents from collection 0579-0115 to this collection. The remaining 9,750 is due to a program change.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to tabulate or publish this information collection.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reason that display would be inappropriate.

Approval is not being sought as no government forms are being used.

18. Explain each exception to the certification statement identified in Item 19 "Certification for Paperwork Reduction Act".

APHIS certifies compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods.

There are no statistical methods associated with the information collection activities used in this program.