

# 2559

March 12, 2007



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RECEIVED

Ms. Mary Bender, Director  
Bureau of Dog Law Enforcement  
The Department of Agriculture  
2301 North Cameron Street, Room 102  
Harrisburg, PA 17110-9408

Re: Dog Law Enforcement, Proposed Regulation #2-152 (#2559)  
Pennsylvania Department of Agriculture

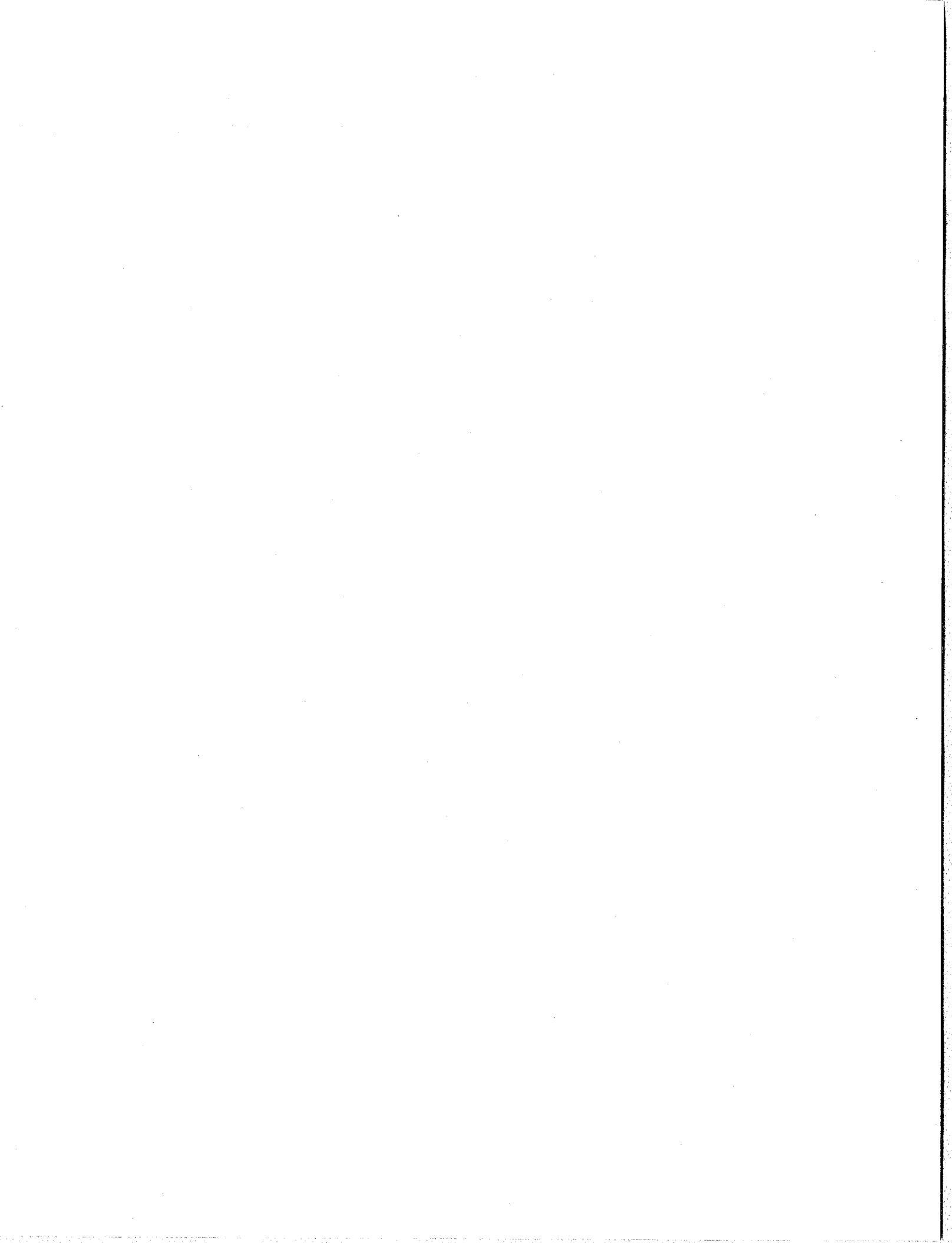
Dear Ms. Bender:

I am writing on behalf of the Department of Laboratory Animal Science at GlaxoSmithKline (GSK), King of Prussia, PA, in order to provide comment on proposed regulations promulgated from the Pennsylvania Dog Law and published in *The Pennsylvania Bulletin* on December 16, 2006. At GSK, animals are only used in research where no alternative is available and GSK scientists constantly strive to reduce the numbers used. GSK is also actively engaged in research to develop and validate in vitro experimental methods. Nonetheless, dogs are still necessary and utilized as experimental models at our site in King of Prussia, PA, and thus we hold a current Pennsylvania Kennel License. At the King of Prussia facilities, we perform essential drug discovery research and safety testing using dogs as well as several other species of animals. GSK strives to exceed industry standards in the care and welfare of all of the animals it uses.

GSK has active membership in the Pennsylvania Society for Biomedical Research (PSBR) and GSK fully supports the comments from the PSBR to the Pennsylvania Dog Law Advisory Board. As the PSBR has stated, biomedical research facilities are unique in their nature and housing requirements when compared with other kennels such as breeding or boarding. GSK dedicates a large amount of resources into all aspects of its laboratory animal programs to ensure optimal quality of the science, and the best possible animal care and welfare.

GSK is registered with the United States Department of Agriculture (USDA) as a research facility and is subjected to unannounced inspections annually. The federal regulations imposed by the USDA and described in the Animal Welfare Act, require that all research institutions using animals have an Institutional Animal Care and Use Committee. At GSK, this committee is comprised of employees of the company including investigator(s), veterinarian(s) and others working with animals, as well as an "outside" member, not affiliated with GSK, but who represents the general community. The IACUC is responsible for performing inspections of all animal facilities at least every six months.

GSK has also met the stringent requirements and undergone the voluntary accreditation program of the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC International). This private non-profit organization ensures that all accredited institutions meet the standards required by law, and are also



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going the extra step to provide excellence in laboratory animal care and use. AAALAC International conducts periodic inspections of all accredited facilities and programs using laboratory animals, and upholds them to standards which are often higher than those set by federal regulators.

GSK agrees with the PSBR, and recommends that research kennels that are registered with the USDA under the Federal Animal Welfare Act, currently under Federal Government inspection, be exempt from Pennsylvania Dog Law regulations. Without such an exemption and an adoption of the proposed regulations as published in the Pennsylvania Bulletin of December 16, 2006, research that benefits both animals and humans, conducted at academic institutions, biotech firms, and pharmaceutical companies (some of which is legally required by the FDA) will be severely curtailed or halted and improvements in animal and human health will be put at risk.

The impact of the proposed Pennsylvania dog laws on the GSK Pennsylvania facility would be extremely costly. The new regulations would essentially require doubling of the existing dog facilities and require tripling of the amount of staff assigned to take care of the current inventory of dogs. It is estimated that it would cost approximately \$18 million in construction, renovation and equipment costs alone to comply with the proposed regulations. Utilizing the proposed regulations will also result in at least an additional \$800,000 per year in operating costs. The proposed laws would be cost prohibitive for GSK, which would most likely result in the transfer of the majority of the research requiring the use of dogs to GSK sites outside of the Commonwealth of Pennsylvania. Along with the transfer of the dog research outside of the state, would also follow a shift in the jobs required to care for the dogs and perform the studies.

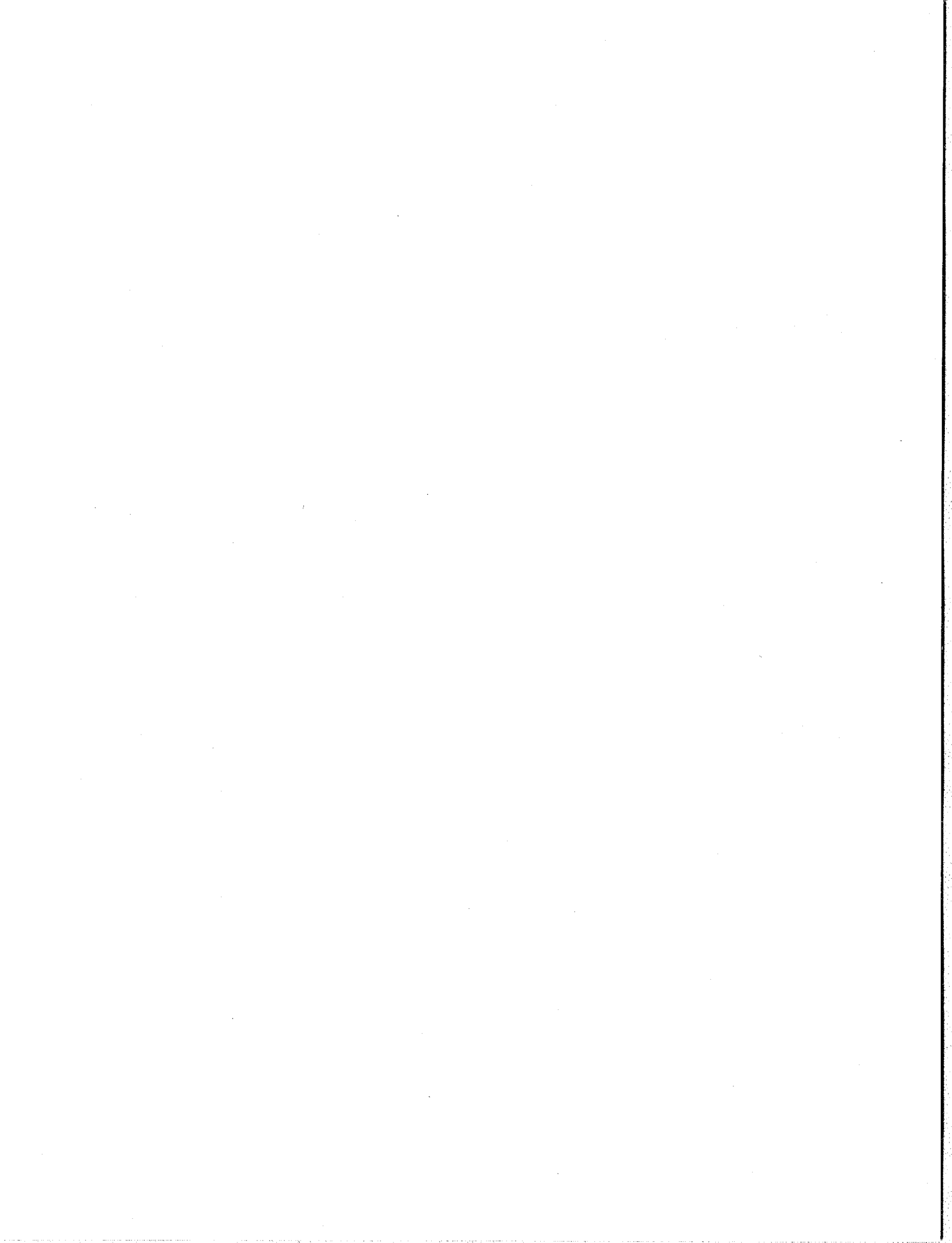
GSK also agrees with the PSBR's recommendation to the Pennsylvania Department of Agriculture to align the regulations for the care of dogs with those established by the United States Department of Agriculture by adopting the standards found in the appropriate sections of CFR Title 9 Chapter 1 subchapter A Parts 1-3, and then to enforce the new regulations. Specific comments on the proposed Dog Law regulations are attached in the appendix to this letter.

Sincerely,



LaVonne D. Meunier, DVM, DCLAM  
Director, Veterinary Medicine and Attending Veterinarian  
GlaxoSmithKline  
709 Swedeland Road  
King of Prussia, PA 19406

cc: Arthur Coccoodrilli, Chairman  
Independent Regulatory Review Commission  
333 Market Street  
14<sup>th</sup> Floor  
Harrisburg, PA 17101



## **Appendix to the letter of March 12, 2007**

GSK has carefully reviewed the proposed Dog Law regulations and have prepared comments on the more problematic areas of the proposed regulations. These comments follow below.

### **From the preamble to the proposed regulations:**

#### **21.23. Space**

The intention of the new language in this section was to address the health and welfare of dogs housed in kennels to make the Department's regulations more consistent with Federal regulations set forth under the Animal Welfare Act (7 U.S.C.A. §§ 2131-2159). The new language addresses space requirements and exercise programs for all dogs kept in a kennel. In fact, the new language is not consistent with the Federal Animal Welfare Act. The proposed language moves further away from the Federal Animal Welfare Act than the current Pennsylvania Dog Law regulations.

### **Fiscal Impact – Private Sector**

This section describes the estimated fiscal impact of the new regulations on the regulated community. The proposed regulation estimates that the costs will range from \$5,000 to \$20,000 per existing kennel for compliance with the new standards.

The figure of \$20,000 is underestimated for research kennels. In fact, at GSK, it is estimated that it will cost approximately \$18 million in construction, renovation, and equipment costs alone to comply with the proposed regulations. Utilizing the proposed regulations will also result in at least an additional \$800,000 per year in operating costs. As mentioned previously, the costs are prohibitive for GSK, and would result in the shift of research requiring dog work to other GSK sites outside of the Commonwealth of Pennsylvania, where regulations governing dog work are more reasonable and in alignment with USDA standards of care. This would also result in the shift of the current workforce required to take care of the dogs outside of the state.

### **Paperwork Requirements**

This section suggests that “the proposed amendments to the regulations will not result in a substantial increase in paperwork”. The record keeping proposed is extensive and is substantially more burdensome than what is presently required.

#### **21.1. Definitions**

The definitions of “attending veterinarian” and “licensed veterinarian” require that the person is a licensed doctor of veterinary medicine as defined by the Veterinary Medicine Practice Act. Veterinarians in biomedical research facilities are not covered by the Veterinary Practice Act and some veterinarians employed by research facilities may have multi-state responsibilities and may, therefore, not be licensed in Pennsylvania. We agree with the PSBR’s suggestion to use the following language found in the section 1.1 of the Federal regulations.

“Attending veterinarian means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary.”

“Licensed veterinarian means a person who has graduated from an accredited school of veterinary medicine or has received equivalent formal education as determined by the Administrator, and who has a valid license to practice veterinary medicine in some State.”

The definition of “sanitize” has been altered to “make physically clean and to remove, neutralize and destroy, to a practical minimum, agents, vectors of disease, bacteria and all infective and deleterious elements injurious to the health of a dog”. This definition is more appropriately the definition of the word “disinfect”. We suggest using the following language found in the section 1.1 of the federal regulations.

“Sanitize means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.”

#### **21.14. Kennel licensure provisions**

(5) Kennel Records: This section describes all requirements of acceptable records for each individual dog, including such details as breed, color, markings, name of kennel where dog originated, address of kennel, kennel license number, date of receipt, etc. While GSK has all of this information on file for all dogs, individual records of each dog do not contain all of these details. At the GSK Pennsylvania site, dogs are maintained on two different campuses, however, some records such as vendor records are held in one central area. Clarification is required as to where such records must be held.

(b) Prohibitions on dealing with unlicensed kennels: This section prohibits any kennel to keep, harbor, board, shelter, sell, give away or in any way accept, deal or transfer any dog from a kennel or establishment operating without a Pennsylvania kennel license. GSK has a site in North Carolina that performs much of the same dog work as the Pennsylvania site. Occasionally, dogs are shared between the North Carolina site and the Pennsylvania site depending on specific study needs. The GSK site in North Carolina does not have a Pennsylvania kennel license. Additionally, the dog vendors that GSK purchases the dogs from are outside of the Commonwealth of Pennsylvania. All of the dogs are purchased from reputable class A dealers located outside of the Commonwealth of Pennsylvania. Compliance with the proposed regulations would seriously jeopardize the ability to procure enough appropriate dogs for essential timely research.

(5) Rabies vaccination and rabies tag requirement: Although all of the dogs currently being purchased by GSK are vaccinated for rabies in accordance with local and state regulations, there may be an occasional research need for vaccine naïve dogs. All dogs are maintained in indoor facilities and in closed colonies with strict containment procedures and veterinary oversight. Therefore, the risk of rabies exposure would be

negligible. Also, even though all our dogs are currently vaccinated at the vendor for rabies and are received with appropriate records indicating the date of vaccination and the name of the vaccine, no rabies tag are issued for any dogs. The dogs do not wear collars, as this increases the risk of possible strangulation or injury. Therefore, tags are not utilized and are not requested from the vendor.

### **21.21. Dog quarters.**

(c) Requirement for adequate drains or gutters in indoor and outdoor housing facilities: At GSK, many of the dogs are housed in cages. For daily sanitization, the cage pans or pan liners are removed daily and replaced with clean pans or liners. For sanitization of the cages, the dogs are moved into clean cages and the dirty cages are removed from the dog room to be placed in the cage wash. The floor in the animal holding room gets a minimal amount of water on it and is cleaned at least daily using a mop and bucket of water with disinfectant. Thus a drain and/or gutter would not be needed to prevent standing water. We agree with the PSBR's suggestion to change the wording to the following:

“Adequate drains or gutters, or other means, shall be provided to prevent standing water in both indoor and outdoor housing facilities and other areas such as outdoor runs and exercise areas.”

(e) Requirement for a wall or partition between primary enclosures to prevent feces and urine from passing into the next enclosure: This requirement greatly reduces the ability of the dogs to have visual and tactile contact, particularly in the areas where runs or pens are utilized as the primary enclosure. For dogs that are required to be individually housed due to study design, we attempt to optimize all opportunities for socialization, including visual and tactile contact. Limiting the possible spread of excrement between adjacent dogs does not greatly increase the possibility of the spread of disease, since all of the dogs share a similar background exposure from the vendor. Rarely a dog may break with clinical signs suggestive of an infectious agent, and then it is quarantined appropriately and treated according to the agent.

### **21.22. Housing.**

(d) and (e) These sections propose requirements for quarantine periods for both new puppies and adult dogs. Since all dogs at GSK are received from closed colonies of known health background, quarantine periods are usually not necessary. However, GSK does routinely quarantine shipments of dogs upon receipt for a period of 15 days as an added precaution to our routine dog preventative programs. Our standard operating procedures allow for the length of the quarantine/acclimation period to be shortened at the discretion of the clinical veterinarian if study timelines dictate an early study start and if all dogs are received in apparent good health. We agree with the PSBR's recommendation to rewrite this section without rigid timelines but with a plan for quarantine/acclimation which has been reviewed and approved by the attending veterinarian.

### 21.23. Space.

(a) The proposed requirements for space dictate that "primary enclosures shall be constructed and maintained to provide sufficient space to allow each dog to turn about freely and to stand erect, sit and lie down in a comfortable, normal position. The dog shall be able to lie in a lateral recumbence (on its side or back) with legs fully extended, without head, tail, legs, back or feet touching any side of the enclosure." The preamble to the proposed regulations states that the new language in this section is intended to make the Department's regulations more consistent with Federal regulations set forth under the Animal Welfare Act. In fact, the proposed additional language makes the regulations less consistent with Federal regulation. Existing state regulations, as well as Federal regulations, ensure that the dog can stand, sit and lie down in normal positions. We agree with the PSBR's recommendation to remove the proposed added language and instead use the following language found in section 3.6(a)(2)(xi) of the Federal regulations.

"Primary enclosures must be constructed and maintained so that they provide sufficient space to allow each dog to turn about freely, to stand, sit, and lie in a comfortable, normal position, and to walk in a normal manner."

(b) This section details the calculation used to identify the minimum amount of floor space required for each dog. The calculation is the same as the one set forth in the Animal Welfare Act in the Federal Register, however, the proposed regulations require doubling of the minimum space required by the federal regulations. Again, this contradicts the Department's stated objective of making the Commonwealth's regulations more consistent with the Federal regulations. By adding the proposed language, the cage size requirement is twice that required by Federal regulation. The Federal regulations do address doubling the required cage size under exercise requirements for dogs that are individually housed that are not provided with another means of exercise. We do not believe that doubling the primary enclosure size requirement will necessarily have a direct benefit on the welfare of the dogs. Research shows that, for purpose bred male laboratory dogs (approximately 10 to 12 kg), enlarging cage size over that currently required by federal regulation, has little or no effect on their activity (Hughes et. al. 1989). For GSK, this single proposed change would be cost prohibitive. GSK would either be required to double all existing Pennsylvania-based dog facilities and equipment, or would be required to reduce by one half all of the existing dog work.

(e) This section states that "each dog shall receive 20 minutes of exercise per day. Dogs shall be observed and supervised during exercise and shall be exercised the following manner..." This is in conflict with the goal of consistency with Federal regulation as well as not showing a direct benefit to the dogs' welfare. Laboratory dogs have been shown to increase activity primarily when stimulated by human interaction and not when left alone in larger areas (Hughes et. al. 1989). Dogs receive more positive stimulation by novel environments, social interaction and human interaction than a large cage size. This is one reason that Federal regulations do not require additional exercise for dogs housed in groups if each animal is provided 100 percent of the space required for an individual dog. Additionally, Federal regulations are not as prescriptive as those proposed by the Department. It is not at all clear on what scientific basis the 20 minute period was established. Federal regulations require an exercise program for dogs but recognize that "The opportunity for exercise may be provided in a number of ways,..." According to Federal regulation, the exercise plans must be developed, documented, and



followed as well as reviewed and approved by the attending veterinarian. In addition, these plans are reviewed for concept, compliance, and animal well-being by the USDA on routine inspection. In a research facility, there are additional safeguards for the animals. In addition to the attending veterinarian, the exercise plan must be reviewed and approved by the Institutional Animal Care and Use Committee. At a minimum, the Committee insures compliance with the plan and checks for the dogs' well-being during their semi-annual inspections of the facility.

(iii) This section describes how dogs must be segregated by weight during exercise. The proposed regulations on compatible groupings by weight are arbitrary. The regulations should be based on actual observed compatibility, rather than size. We agree with the PSBR and suggest using the following language found in section 3.6(c)(2) of the Federal regulations.

“All dogs housed in the same primary enclosure must be compatible, as determined by observation. Not more than 12 adult nonconditioned dogs may be housed in the same primary enclosure. Bitches in heat may not be housed in the same primary enclosure with sexually mature males, except for breeding. Except when maintained in breeding colonies, bitches with litters may not be housed in the same primary enclosure with other adult dogs, and puppies under 4 months of age may not be housed in the same primary enclosure with adult dogs, other than the dam or foster dam. Dogs with a vicious or aggressive disposition must be housed separately.”

(iv) This section allows only the Department to exempt a dog from exercise for a period of time, only if a licensed veterinarian has determined the dog should be exempt and has submitted their determination in writing to the Department. The submission must include the specific medical condition, the reason for the exemption and the time period for the exemption. This proposal will necessitate a lapse of time from the initial submission to the Department until comment will be received from the Department. The amount of time that may lapse while waiting for comment from the Department could be significant and devastating to a critically injured dog, if the clinical veterinarian is not allowed to exercise his/her own judgment to exempt a dog from exercise. We suggest using the Federal regulatory concept that allows the attending veterinarian to exempt a dog from the exercise program for medical reasons. Also, for scientific reasons, exercise may be contraindicated for a research protocol. In that case, according to Federal regulations, the Institutional Animal Care and Use Committee may exempt the dogs from exercise. There is no such provision in the Department's proposed regulations possibly endangering the research or jeopardizing the welfare of the dog. We agree with the PSBR and suggest adding an opportunity for exemption from exercise using the language below found in section 3.8(d) of the Federal regulations.

“(1) If, in the opinion of the attending veterinarian, it is inappropriate for certain dogs to exercise because of their health, condition, or well-being, the dealer, exhibitor, or research facility may be exempted from meeting the requirements of this section for those dogs. Such exemption must be documented by the attending veterinarian and, unless the basis for exemption is a permanent condition, must be reviewed at least every 30 days by the attending veterinarian.

(2) A research facility may be exempted from the requirements of this section if the principal investigator determines for scientific reasons set forth in the research

proposal that it is inappropriate for certain dogs to exercise. Such exemption must be documented in the Committee approved proposal and must be reviewed at appropriate intervals as determined by the Committee, but not less than annually. (3) Records of any exemptions must be maintained and made available to (USDA) Department officials [or any pertinent funding Federal agency] upon request.”

(v) This section describes the record keeping requirements for documentation of exercise. “Daily records of exercise shall be kept for each dog in the kennel. The records, at a minimum, must set forth: (A) the breed, color, markings, sex, approximate weight and age of each dog or when applicable, the microchip number of each dog; (B) the date and the time period each dog was exercised and whether the exercise was on a leash or in an exercise area; and (C) any medical exemption written by a veterinarian licensed to practice in this Commonwealth. At GSK accurate records are kept detailing exercise for every dog. However, not all of the specifics detailed in (A) are kept on the daily exercise logs. This information can be found elsewhere in each dog’s individual health record (kept in electronic format) or in the vendor’s records which are kept in one central location. We suggest for (A) and (B), the regulations allow for group records and identifying dogs by number that can be traced back to the dog’s individual information which may be maintained elsewhere. In addition (C) appears to be in conflict with (iv) that states that the Department issues the exemption from exercise. The proposed regulations need clarification on this issue.

#### **21.24. Shelter, housing facilities and primary enclosures.**

(5.) Housing facilities and areas used to store food or bedding must be free of any accumulation of trash, waste, garbage or other discarded material: At GSK, trash, bedding and waste is removed from each animal room at least daily. This discarded material is moved to another area of the facility that is dedicated for temporary trash storage, and that is distant from any animal rooms. The discarded material may be held for a short period of time in this area until the material is removed from the facility by the waste handler. If the intent is to keep waste material or possibly contaminated material away from the dogs, then this section should be reworded to specify that trash should not be allowed to accumulate in an animal room.

(7.) Animal waste including bodily fluids, food waste, soiled bedding, dead animals, garbage and water that is dirty and no longer potable must be removed from all areas of the housing facility and disposed of on a daily basis...: Again, at GSK there are areas outside of the animal rooms but still within the housing facility that are dedicated for storage of waste materials until they are retrieved by the appropriate waste handler. Animal carcasses are held in chest-type freezers that are conveniently located on each floor of the housing facility, but outside of any animal rooms. The freezers are emptied on an as-needed basis. Also, small amounts of blood in syringes are regularly discarded into “sharps” containers which for personnel safety reasons are required to be held in each animal room where injections may be taking place. GSK recommends that this section be reworded to indicate that waste materials should not be allowed to accumulate in the “animal room”, and not use the phrase “housing facility”.

(8) This section describes the records that must be maintained to include the date and time of day the housing facility was: (i) cleaned; (ii) sanitized; (iii) each individual cage, dog box or primary enclosure was cleaned; (iv) each food and water bowl was sanitized; and, (v) the date and time new food and potable water was provided each dog. Accurate record-keeping is integral to sound research, and all staff at GSK are trained to keep accurate complete records on activities involving animals. However, recording the time of day that each of these activities occurs for every dog would be overly burdensome and unnecessary. Daily dog husbandry practices are typically performed on the group of dogs currently residing in a dog room, and documentation reflects that the room of dogs was fed, not the individual dog. The records that we currently maintain for the dogs have been acceptable with the USDA, FDA and AAALAC. Also, the proposed regulations are using the word "sanitize" incorrectly. Sanitizing is not the same as cleaning. Federal regulations require that excreta and food waste be removed from primary enclosures daily to prevent an excessive accumulation of waste, to prevent soiling of the dogs and to reduce disease hazards, insects, pests and odors. Federal regulations require sanitization of the primary enclosure once every two weeks. Sanitization of the primary enclosures of all dogs every day would be overly burdensome and unnecessary since the Federal regulations have already been proven to be adequate to maintain the health of the dogs. In order to sanitize cages at GSK, cages are run through the cage wash unit. In order to sanitize every dog cage every day, our current dog staffing requirements would need to be at least doubled, the number of additional cages needed would need to be almost doubled in order to have clean cages to move dogs into, and new facilities with new cage wash units would need to be installed.

(9) The housing facility must have and be equipped to provide potable water for all the dogs' drinking needs and for all other animal husbandry requirements: At the GSK Pennsylvania site, grey water is utilized for the initial wash cycle of the cage wash units. This practice is being performed to be in compliance with local ordinances in order to save water resources. The Township of Upper Merion has established an upper limit of daily water usage for the GSK site in Upper Merion Township. If GSK's usage goes over the upper limit, the company will be fined up to \$25,000 per day. Taking into account the proposal to require sanitization of every primary enclosure every day, the amount of water wasted would be exorbitant, and would most likely exceed the upper limit allowed by the local ordinance.

(i) Where the kennel is an indoor kennel with no outside runs, a gutter and drain shall be provided for sluicing waste waters during kennel cleaning. The kennels must have adequate holding facilities to allow a dog to be outside its primary enclosure during the washing of that primary enclosure and until there has been adequate drying of the primary enclosure: At the GSK Pennsylvania site, indoor kennels are cleaned daily without the use of excessive amounts of water. Usually, the dogs are removed from their kennel and allowed to run in the hallway while their kennel area is cleaned. The floors are squeegeed dry before the dog is returned to the kennel. The kennel floor is not completely dry, but will not have any standing water. We suggest that the wording be changed to be consistent with the Federal regulations:

"When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs [and cats] must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process."

(ii) Floor or surface drains and gutters must be at least 6 inches in diameter: Most of the drains that are in place in the GSK dog facilities are 4 inches in diameter as required by Federal regulations. These drains are adequate for handling the amount and type of waste that is produced. Imposition of this regulation would require major renovations to our facility without any real benefit to the dogs.

(v) Drains and gutters shall be sanitized at least once daily and flushed immediately after cleaning with potable water to prevent sanitation problems: Daily sanitization of drains is overly burdensome and not required to maintain the health of the animals. We are unclear as to the reason for flushing only with potable water. Clarification is needed.

(vii) This section describes the required slope of the floor in kennels – at least 1/8-inch per foot. This seems to be overly prescriptive. Many of the kennel floors would need to be replaced at GSK, resulting in substantial renovation costs, even though there would be no benefit to the health of the dogs.

(18) Kennel facilities shall be cleaned and sanitized once every 24 hours in a manner consistent with this chapter: This statement is very broad, and clarification is needed on what is considered to be part of the kennel facility. We also question the use of the word “sanitized”, since the Department’s definition of the word is actually more consistent with the word “disinfect”. This proposal seems overly burdensome with no real benefit to the health of the dogs. We suggest using the language found in section 3.11(c) of the Federal regulations.

“Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin.”

## **21.25. Temperature control.**

(c) Auxiliary temperature control and air movement from fans, blowers or air conditioners shall be provided when the ambient temperature is 85° F (29.5° C) or higher: The words “temperature control” should be replaced with the word “ventilation”. This would make the regulation consistent with Federal regulations and the Department’s proposed regulation in Section 21.26 (b).

(d) Indoor kennels shall have a heating source sufficient to assure a slab temperature of not less than 35° F and not more than 55° F during heating season: It appears as though the “55 degrees” is incorrect, and inconsistent with the previous section.

(2) Cooling. This section states that “the ambient temperature in the facility may not rise above 85° F.” We believe that the Commonwealth should use the language found in section 3.2(a) of the Federal regulations.

“The ambient temperature must not fall below 45 F (7.2 C) for more than 4 consecutive hours when dogs or cats are present, and must not rise above 85 F (29.5 C) for more than 4 consecutive hours when dogs or cats are present.”

## 21.26. Ventilation in housing facilities.

(1) Kennels must be equipped and meet the minimum air flow required for control of moisture condensation under severe conditions, which is 0.8 to 1.0 cubic feet per minute per square foot of floor area: At GSK, all animal rooms are equipped with engineering controls to maintain appropriate temperature and humidity levels for each species as mandated by the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals. The factors affecting animal room humidity are many, including the temperature in the animal room, the ambient temperature, the animal stocking rate, and certain procedures being performed in the room, such as cleaning and mopping. Therefore, control of humidity in an animal room is complex and is not solely dependent on ventilation.

(3) The kennel building must include ground level ventilation to assure dry kennel run floors during cold weather: These proposed regulations seem overly prescriptive and arbitrary. Humidity may be reduced by means other than ventilation such as engineering methods. Compliance with this proposal would require major renovations to the GSK Pennsylvania facilities without any benefit to the dogs.

(4) The ventilation system for latrines and support buildings must be separate from the ventilation system for the kennel building. Kennel support buildings, such as supply buildings, must have a ventilation system that provides at least one air exchange per hour: Additional clarification is requested. It appears as though completely separate ventilation systems would be required for support areas, which is unnecessary. One air handler can be engineered to bring 100% fresh air into all rooms of a facility and then exhaust 100% of that air from all rooms. Completely separate air handling systems would not be required to accomplish this. In addition, HEPA filtration of re-circulated air is not considered in this proposed regulation. In order for GSK to comply with this regulation, it would be necessary to install several new air handlers in each existing facility. We suggest rewriting this proposed regulation to state that unfiltered air may not be exhausted from animal holding rooms into personnel areas or dropping the regulation entirely. We also do not understand why a building that is used to store equipment such as clean caging would be required to have a ventilation system and recommend deleting the second sentence.

(5) The ventilation requirements may be achieved through design of the building shell and natural air flow or by means of auxiliary air movement systems. Where auxiliary air movement systems are required or utilized to achieve the required air exchanges, the kennel must still have doors and windows which can be opened to allow air flow in the event of a system malfunction: It would not be acceptable to have open windows to the outside within an animal facility. Research facilities do not design windows or doors to the outside into animal holding rooms. This is for security, biosecurity, and scientific reasons. The dog colonies at GSK are closed colonies with high health standards. Dogs are typically purchased from only one vendor with a known health status. Opening a window could result in contamination of the colony with pathogens which would jeopardize the health of the dogs and the research. In the case of a ventilation malfunction at GSK, back-up systems are in place such as redundant HVAC systems and back-up generators. GSK also has written emergency contingency plans in the event of a catastrophic event that renders back-up systems ineffective.

### 21.27. Lighting and electrical systems.

(1) Dogs housed in indoor and sheltered kennel facilities shall be provided a regular diurnal lighting cycle. The lighting must be uniformly diffused throughout the animal facility. Primary enclosures must be placed to protect the dogs from excessive light. Lighting in the kennel building and area containing the primary enclosures must be at least 10-foot candles. At least 20-foot candles of light must be provided in all bathing, grooming and toilet areas and 70-foot candles of light shall be provided in support buildings, including food preparation and storage areas.: These proposed regulations are unnecessarily prescriptive and not based on current guidelines for construction of animal facilities. The National Institutes of Health design guidelines for the construction of research animal facilities are:

<u>Space</u>	<u>Lighting levels (footcandles)</u>
Animal Facilities	25-74 (variable through dimming)
Offices	49-74
Corridors	30-49
General Storage	19-30

We suggest deleting the proposed language and replacing it with the language below that is found in section 3.2(c) of the Federal regulations.

“Indoor housing facilities for dogs and cats must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the dogs and cats. Animal areas must be provided a regular diurnal lighting cycle of either natural or artificial light. Lighting must be uniformly diffused throughout animal facilities and provide sufficient illumination to aid in maintaining good housekeeping practices, adequate cleaning, adequate inspection of animals, and for the well-being of the animals. Primary enclosures must be placed so as to protect the dogs and cats from excessive light.”

(b) Electrical systems. Receptacle circuits in areas to be washed down or subjected to spraying shall be provided with ground fault circuit interrupters: All of the GSK animal facilities electrical systems have already met existing building code requirements. In order to be compliant with this regulation, GSK would need to rewire most of the animal facilities, which is not feasible. Also, the all-weather type outlets are not currently required for indoor facilities. A spring cover should be sufficient.

### 21.28. Food, water and bedding.

(a) Wet, moldy, soiled or inedible food shall be disposed of promptly--meaning within 2 hours of feeding--and feeding bowls shall be cleaned with detergent and hot water at least daily and always prior to the next feeding. Water bowls shall be cleaned with detergent and hot water on at least a daily basis or whenever urine, stools or vomit are present in the bowl, whichever is more frequent: At GSK we frequently add water to dry feed in order to increase the palatability of the feed for dogs that have a reduced appetite. Also, we frequently feed canned food, which contains a significant amount of water. We also do not believe that it is necessary to wash feed and water bowls with detergent daily, as

this would have no additional benefit for the dogs. We recommend using the language found in section 3.11(b) of the Federal regulations.

“(1) Used primary enclosures and food and water receptacles must be cleaned and sanitized in accordance with this section before they can be used to house, feed, or water another dog, or social grouping of dogs.

(2) Used primary enclosures and food and water receptacles for dogs must be sanitized at least once every 2 weeks using one of the methods prescribed in paragraph (b)(3) of this section, and more often if necessary to prevent an accumulation of dirt, debris, food waste, excreta, and other disease hazards.

(b) Potable water shall be available to the dogs at all times unless otherwise directed by a veterinarian. The water must be free of stools, urine, vomit and other contaminants at all times: Most of the dogs at GSK receive water through an automatic watering system. Occasionally, a water bowl is offered to a dog if there are concerns about the dog understanding how to use the automatic waterer, or if there are concerns about the dog being able to reach the waterer. When water bowls are being used, it would be impossible to be in compliance with this proposed regulation at all times. If a dog spills the water from its dish, or if a dog vomits or defecates in its dish, the facility would be in immediate violation of the regulation. We recommend using more appropriate language found in section 3.10 of the Federal regulations.

“If potable water is not continually available to the dogs and cats, it must be offered to the dogs and cats as often as necessary to ensure their health and well-being, but not less than twice daily for at least 1 hour each time, unless restricted by the attending veterinarian. Water receptacles must be kept clean and sanitized in accordance with Sec. 3.11(b) of this subpart, and before being used to water a different dog or cat or social grouping of dogs or cats.”

(c) Self-feeders and waterers may be used but shall be sanitized on a daily basis to prevent mold, deterioration, contamination or caking of feed: Automatic waterers are used routinely at GSK. The waterers are not sanitized daily, but are maintained by passing chlorinated water through the lines and the mixers. This practice is safe and proven to be effective in delivering water of acceptable microbial quality to the dogs as evidenced by periodic water sampling and microbial monitoring. The proposed regulations are burdensome and unnecessary.

## **21.29. Sanitation.**

(1) Kennels, including the kennel building, areas in which dogs are housed, all interior surfaces, the primary enclosure of each dog, outdoor runs associated with both indoor and outdoor kennels, and drains and gutters shall be sanitized and disinfected daily (every 24 hours), using only those disinfecting products approved by a licensed veterinarian: Again, GSK agrees with the PSBR and questions the use of the words “sanitized and disinfected”. As previously stated, the definition of the word “sanitize” is more appropriately the definition of the word “disinfection”. We would like the Department to clarify what they would like “sanitized and disinfected” daily. This proposed regulation is broadly written and overly burdensome with no real benefit. If the Department is referring to the premises, we suggest using the language found in section 3.11(c) of the Federal regulations.

“Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin.”

(2) A dog may not be placed in a primary enclosure previously occupied unless the enclosure has been sanitized and disinfected. The primary enclosure and runs associated with that primary enclosure shall be sanitized and disinfected whenever an animal is removed from that primary enclosure and prior to being occupied by another animal. Exercise areas shall be sanitized and all stools removed prior to the next group of dogs being exercised in that area: We question the use of the word “disinfected”. We suggest using the following language from section 3.11 (b)(1) of the Federal regulations.

“Used primary enclosures and food and water receptacles must be cleaned and sanitized before they can be used to house, feed, or water another dog or cat, or social grouping of dogs or cats.

For exercise areas, we do not believe that it is necessary to sanitize the area between groups of dogs, therefore, we recommend that the word “sanitized” in the last sentence of 21.29 (2) be changed to “cleaned”.

(3) Dogs shall be removed from their enclosures while the enclosure is being sanitized and washed down: Sanitization and daily cleaning of a primary enclosure are two separate procedures. We agree that dogs need to be removed from the enclosure during the sanitization process. However, for daily cleaning of the primary enclosure, it is not necessary to remove the dog as long as the dog is able to avoid getting wet during the procedure. The requirement that the dog be removed for washing the enclosure is also inconsistent with Federal regulations. We suggest using the following language which is found in section 3.11(a) of the Federal regulations.

“When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs [and cats] must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process.”

(4) Before washing down concrete runs, stools shall be removed with a shovel to prevent them from splashing into adjacent runs, on the walls of the kennel, or on the dog. The method of disposing of stools depends on local conditions and the type of sewage system present. If stools must be carried from the area in cans, the cans shall be cleaned and disinfected on a daily basis: The use of a shovel to remove stools before washing down runs is too prescriptive. There are other ways to remove stools such as vacuum systems which have been employed at GSK. Additionally, there is no provision for putting a liner in the trash cans for the stools. This would eliminate the need for “disinfecting” the can daily and it can then be sanitized on an as-needed basis.

(5) One of the causes of bacterial skin infections and bacterial ear infections in kennels is the high humidity in the kennels. For this reason, when cleaning or sanitizing the kennels animals shall be removed from their primary enclosure and runs prior to cleaning or sanitizing the primary enclosure or run. The runs and floor areas associated with the



primary enclosure shall be squeegee dried and the primary enclosure shall be dried prior to putting the animal back in the run or primary enclosure: The premise for this statement is incorrect. High humidity is not caused by wet dogs but rather lack of proper humidity controls and/or improper ventilation. This section should be consistent with the Federal regulations and the dogs should not have to be removed if the enclosure is large enough to ensure the animals will not be harmed, wetted, or distressed in the process. Wet-vacs and mop and bucket, routinely used in research facilities, would work satisfactorily for drying the enclosure but are excluded by this proposed regulation. In addition, it would be overly burdensome to dry every enclosure before the animal returns to it. We suggest that this proposed regulation be broadened and brought into consistency with Federal regulations which require the removal of standing water rather than the enclosure being dried.

## **KENNELS--RECORDS**

### **21.41. General requirements.**

(e) In addition to the records required under section 207 of the act, every keeper of a kennel shall keep a record of the following for each dog housed in the facility: (1) the date, time and detail of daily feedings, cleaning of kennel, and changing and refreshing potable water; (2) the date, time and detail of exercise activity of the dog; (3) the date, time and detail of any medication administered to a dog; and (5) the date and time of any veterinary care administered: As previously stated, GSK is dedicated to maintaining high quality records of all animal work. However, it is unnecessary to record times for all of these procedures, especially when detailed standard operating procedures are available that set specific limits and timelines.

### **21.42. Bills of sale.**

(b) It shall be a violation of the act and this chapter for a kennel owner, operator or agent to purchase, accept, sell on behalf of or transport a dog from a kennel required to be, but not licensed under section 207 or 209 of the act without written permission from the Department: As mentioned previously, GSK has another site in North Carolina that conducts research with dogs. Occasionally, dogs are shared between the two sites, and the North Carolina site does not have a Pennsylvania kennel license. Additionally, all of our dogs are purchased from a vendor which is located outside of Pennsylvania.

