April 16, 2018

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Via certified mail (return receipt requested) and e-mail (kevin.a.shea@aphis.usda.gov; tonya.g.woods@aphis.usda.gov; foia.officer@aphis.usda.gov)

Re: Freedom of Information Act Appeal of USDA's Decision to Withhold Information Concerning FOIA Request 2017-APHIS-02031-F.

Dear Mr. Shea and Ms. Woods,

On behalf of the People for the Ethical Treatment of Animals ("PETA"), I hereby appeal the United States Department of Agriculture's ("USDA") decision to withhold information contained in agency records that are subject of PETA's Freedom of Information Act ("FOIA") request number <u>2017-APHIS-02031-F</u>.

On February 09, 2017, Katherine Groff submitted a FOIA request on behalf of PETA for, *inter alia*, all photographs from March 2016 of Pi Bioscientific Inc. - Site 001 (Certificate Number: 91-R-0072, Customer Number: 331329) and of the inspection site affiliated with Robert Sargeant (Certificate Number: 93-R-0283, Customer Number: 1115) taken by the USDA or otherwise in the agency's possession.

Pi Bioscientific Inc. is a research facility regulated under the Animal Welfare Act ("AWA") that uses animals to produce antibodies—despite the availability of nonanimal methods—and that is a chronic violator of the AWA. The facility affiliated with Robert Sargeant is also a research facility regulated under the AWA that uses



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animals to produce antibodies. Both of these facilities were cited by the USDA in March 2016 for a host of AWA violations—Pi Bioscientific for twenty (20) violations over just six (6) days that impacted dozens of animals, including two (2) repeat violations and two (2) direct violations for failing to provide adequate veterinary care to two (2) dozen goats who were "afflicted with various ailments and severe medical problems to include emaciation, diarrhea, lameness, overgrown hooves, coughing and upper respiratory disease."¹ That same month Sargeant was cited for violating five (5) AWA standards, including failing to adequately describe euthanasia methods.² Inspection reports detailing these violations were posted to the USDA's website in 2016 with only signatures redacted.

Nearly a year after PETA submitted its FOIA request, on January 16, 2018, the Animal Care ("AC") program of the Animal and Plant Health Inspection Service ("APHIS") of the USDA responded to the request, refusing to acknowledge whether photographs pertaining to Pi Bioscientific for the relevant time period existed (a Glomar response), and providing eight (8) completely redacted pages pertaining to Sargeant.³

As detailed further below, the USDA's use of the Glomar response for Pi Bioscientific was improper and unlawful. The USDA stated:

Confirmation of the existence of such records would itself reveal exempt information. To acknowledge the existence of records would constitute a clearly unwarranted invasion of personal privacy pursuant to Exemption 6 of the FOIA. Responsive records, if they existed, would be exempt from disclosure under Exemptions 5, 6, and/or 7C.

Because of the obvious possibility of embarrassment, harassment, intimidation, or other personal intrusions, we find that to even acknowledge that responsive records may exist pertaining to any portion of your request would result in a substantial invasion of privacy.⁴

The requested photographs, however, are *mandated* to be taken by AC pursuant to the USDA's Animal Welfare Inspection Guide procedures for direct veterinary care noncompliant items and repeat noncompliant items, both of which Pi Bioscientific was cited for during the relevant time period, as well as for corrected direct veterinary care citations, which AC is required to reinspect for.⁵ Furthermore, even if this were not the case, the inspection photograph records requested of Pi Bioscientific would not

¹ Exhibit 3. Pi Bioscientific, Inc. (Certificate Number 91-R-0072) USDA Inspection Reports.

² Exhibit 4. Robert Sargeant facility (Customer Number: 1115) USDA Inspection Report from March 17, 2016.

³ Exhibit 1. Email from the USDA to Katherine Groff, Final Disposition, FOIA Request 2017-APHIS-02031-F, Jan. 16, 2018; Exhibit 2. Eight (8) redacted pages provided by the USDA in response to records requesting records in the agency's possession pursuant to the March 2016 USDA inspection of the facility associated with Robert Sargeant (Certificate Number: 93-R-0283, Customer Number: 1115). ⁴ Ex. 1 at p. 2.

⁵ United States Department of Agriculture Animal Welfare Inspection Guide (2017), Required Inspection Procedures, Inspection Photographs at pages 2-15, 2-12, 3-30,

https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf.

properly fall within any FOIA exemption. All responsive photographs of Pi Bioscientific should be provided to PETA.

The USDA's extensive redactions of the Sargeant photographs was also improper and unlawful. In redacting these pages, the USDA stated "the release of the identifying information does not shed any light on APHIS activities" (for Exemption 6), and did not provide any justification whatsoever for its redactions made pursuant to Exemption 7(C).⁶

The USDA failed to meet its burden in withholding this information under the FOIA, as "the burden which the FOIA specifically places on the Government to show the information withheld is exempt from disclosure cannot be satisfied by the sweeping and conclusory citation of an exemption."⁷ Furthermore, since these records would be required to be released under the FOIA, withholding may also not occur pursuant to the Privacy Act.⁸ Moreover, even if some of the information may be withheld, it does not appear that the USDA provided all "reasonably segregable" portions of the requested records.⁹

Consequently, all of the records requested from the USDA should be provided in full—or, alternatively, if it is determined that any information may properly be withheld, all reasonably segregable portions of the requested records must be provided.

I. <u>A Glomar Response for Pi Bioscientific Was Improper.</u>

In rare and limited circumstances, in response to a FOIA request, when the government has found that its mere acknowledgement of the existence of responsive records would, itself, reveal information exempt under the FOIA, it may, then, look to the process of refusing to confirm or deny the existence of the records responsive to the request.¹⁰ This response to a FOIA request is known as a Glomar response.¹¹ In these cases, in order to properly provide a Glomar response to a request, the government must first treat the fact of the *existence* of the documents as the request, and proceed with the FOIA's exemption procedures.¹²

As discussed further in the subsections below, the USDA's use of the Glomar response to the records requested of Pi Bioscientific was improper, for three (3) independent reasons: (1) the records do not meet the threshold requirements for a Glomar response, (2) the public is already aware that the responsive records exist—as they are required to exist pursuant to the USDA's establish inspection

⁶ Ex. 1 at p. 2.

⁷ Mead Data Central, Inc. v. U.S. Dep't of Air Force, 566 F.2d 242, 251 (D.C. Cir. 1977).

⁸ 5 U.S.C. § 552a(b)(2).

⁹ See Mead Data Cent., Inc., 556 F.2d at 260.

¹⁰ Phillippi v. CIA, 546 F.2d 1009, 1012-13 (D.C. Cir. 1976).

¹¹ See *id*.

¹² *Id.* ("The Agency [must] provide a public affidavit explaining in as much detail as is possible the basis for its claim that it can be required neither to confirm nor to deny the existence of the requested records.")

procedures—and (3) the responsive records are not protected from disclosure by any FOIA exemption. Accordingly, the USDA cannot withhold these records, and they must be disclosed in full.

A. The records do not meet the threshold requirements for issuance of a Glomar response.

The USDA's denial letter, in the instant matter, states that the agency considers whether the confirmation of the existence of certain records would reveal exempt information, and the following four (4) threshold circumstances exists when issuing a Glomar response: (1) the request is made by a third party; (2) the request is for information about a person identified by name; (3) the named individual is not deceased; and (4) the individual has not given the requester a waiver of his privacy rights.¹³

While the denial letter merely states that "all of the . . . circumstances exist,"¹⁴ it is clear that the records regarding Pi Bioscientific Inc., a corporation, *are not* records requested "about a person identified by name." Moreover, it is also clear from the plain language of the above-referenced threshold requirements that these circumstances were designed to protect *individuals* and their privacy interests, and not *corporations*.¹⁵ Corporations, such as Pi Bioscientific, do not have personal privacy interests protected under the FOIA, nor do they meet Glomar's threshold requirement that they would be a "person identified by name."¹⁶ Consequently, because the records were requested from a corporation, they clearly fail to meet the threshold requirements the USDA provided of being subjected to a Glomar response.

B. <u>A Glomar response is improper and unlawful for information the public already knows</u> exists.

The FOIA request in the instant matter requested, *inter alia*, the photographs of Pi Bioscientific that the agency had in its possession from March of 2016. The USDA's Animal Welfare Inspection Guide mandates that "Photographs or videos **must** be taken to document photographable noncompliant item(s) ("NCIs")" in instances including "Direct, Critical, or Repeat NCIs; Direct NCIs that have been corrected; and Veterinary Care NCIs involving animals."¹⁷ Moreover, for veterinary care citations, the USDA must "take photograph(s) or video(s) of every animal covered by the citation" and for facility violations the USDA must take "representative photos to prove that there was an NCI."¹⁸ Finally, "[s]upervisors may have inspectors take additional photographs, in addition to the required photographs listed above."¹⁹

¹³ Ex. 1 at p. 3; see also Pugh v. F.B.I., 793 F. Supp. 2d 226, 232 (D.D.C. 2011).

¹⁴ Ex. 1 at p. 3.

¹⁵ See also, Pugh, 793 F. Supp. 2d at 232.

¹⁶ See, e.g., *id.; FCC v. AT&T, Inc.*, 562 U.S. 397, 409-10 (2011) ("The protection in FOIA against disclosure of law enforcement information 'on the ground that it would constitute an unwarranted invasion of personal privacy does not extend to corporations.")

¹⁷ United States Department of Agriculture Animal Welfare Inspection Guide (2017), Required Inspection Procedures, Inspection Photographs 2-15,

https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf. ¹⁸ *Id.*

¹⁹ *Id*.

According to inspection reports that were posted to the USDA's website, in March of 2016, over the course of two (2) inspections conducted by the USDA, Pi Bioscientific was cited for twenty (20) Animal Welfare Act violations, including three (3) direct violations (with two (2) of these being for veterinarian care), three (3) repeat violations, and one (1) facility violation.²⁰ Accordingly, pursuant to the USDA's inspection requirements, USDA inspectors were *required* to take photographs and video(s) throughout the course of the inspections of Pi Bioscientific's facility in March of 2016, due to the nature of Pi Bioscientific's AWA violations. Indeed, because the direct veterinary care violations impacted two (2) dozen animals, and the inspection guide requires photographs of every animal impacted by such violations, the agency was required to take *many* photographs. The guide also requires reinspection for direct veterinary citations, and photographs of corrections of such violations.²¹

Consequently, it is clear based on publicly available information that responsive records exist, as they are mandated to exist pursuant to the USDA's established procedures. An agency may not issue a Glomar response and refuse to confirm or deny a record's existence when the record "unquestionably exists."²² Thus, the agency's issuance of a Glomar response for the photographs in the USDA's possession as a result of their numerous inspections of Pi Bioscientific in March of 2016 is incorrect, and cannot be used to withhold the records.

C. <u>A Glomar response was improper and unlawful because the requested records are not exempt under the FOIA.</u>

A Glomar response is valid only "if the fact of the existence or nonexistence of agency records falls within a FOIA exemption."²³ "Because Glomar responses are an exception to the general rule that agencies must acknowledge the existence of information responsive to a FOIA request and provide specific, non-conclusory justifications for withholding that information, they are permitted only when confirming or denying the existence of records would itself 'cause harm cognizable under an FOIA exception."²⁴ "In determining whether the existence of agency records *vel non* fits a FOIA exemption, courts apply the general exemption review standards established in non-Glomar cases."²⁵

In refusing to acknowledge the existence of responsive records pertaining to Pi Bioscientific, the USDA stated that "[t]o acknowledge the existence of records would constitute a clearly unwarranted invasion of personal privacy pursuant to Exemption 6 of the FOIA." However, the release of these records would not invade personal privacy. Moreover, the USDA did not provide any substantive argument for any exemptions under the FOIA, instead conclusorily asserting that "[r]esponsive records, if they existed,

²⁰ Ex. 3.

²¹ United States Department of Agriculture Animal Welfare Inspection Guide (2017), Required Inspection Procedures, Inspection Photographs 2-12, 3-30

https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf.

²² See Nuclear Control Inst. v. U.S. Nuclear Regulatory Comm'n, 563 F. Supp. 768, 772 (D.D.C. 1983).

²³ Wolf v. CIA, 473 F.3d 370, 374 (D.C. Cir. 2007).

²⁴ *ACLU v. CIA*, 710 F.3d 422, 426 (D.C. Cir. 2013).

²⁵ Wolf, 473 F.3d at 374.

would be exempt from disclosure under Exemption 5, 6, and/or 7C.²⁶ As demonstrated *infra*, moreover, the responsive records cannot lawfully be withheld pursuant to any of these exemptions. Accordingly, they must be provided in full.

1. The agency has not met its burden of demonstrating that the withheld information would be exempt from disclosure pursuant to an exemption under the FOIA.

The FOIA exemptions "are to be narrowly construed,"²⁷ "in such a way as to provide the maximum access consonant with the overall purpose of the Act,"²⁸ and the "burden is placed upon the government agency to establish that a given document is exempt from disclosure."²⁹ The "FOIA compels disclosure in every case where the government does not carry its burden of [showing] that one of the statutory exemptions apply."³⁰ It is well settled that conclusions, unsupported by the agency's *reasons* for the application of an exemption, are insufficient to support a decision to withhold information from the public.³¹ Rather, the agency "must provide a relatively detailed justification, *specifically* identifying the reason why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply."³²

The FOIA requires agencies to provide requested information unless the agency *demonstrates* that a statutory exemption applies.³³ Indeed, the "presumption favoring disclosure . . . is at its zenith under Exemption 6."³⁴As stated above, the USDA provided *no* substantive discussion of the applicability of Pi Bioscientific's records being protected from disclosure under Exemptions 5, 6, or 7(C).

Failing either to provide the requested information or to adequately explain why it is not being disclosed violates the FOIA. Further, PETA is at a stark disadvantage in preparing this appeal as it lacks any substantive discussion for the agency's proposed application of the FOIA's exemptions to the records— a threshold requirement to providing a Glomar response—and consequently, the information necessary to craft its arguments.

²⁶ Ex. 1. Although the agency did provide a brief discussion of Exemption 6, that discussion appears to pertain to the partial withholdings from the records regarding Sargeant, *see id.* at 1-2, and are accordingly discussed in Part II below. No substantive discussion of the applicability of Exemption 6 or any other exemptions to the records pertaining to Pi Bioscientific was provided.

²⁷ Church of Scientology of Cal. v. U.S. Dep't of Army, 611 F.2d 738, 742 (9th Cir. 1979).

²⁸ Vaughn v. Rosen, 484 F.2d 820, 823 (D.C. Cir. 1973).

²⁹ Id.

³⁰ Goldberg v. U.S. Dep't of State, 818 F.2d 71, 76 (D.C. Cir. 1987).

³¹ See Mead Data Cent., Inc., 566 F.2d at 251.

 $^{^{32}}$ Id. (emphasis added).

³³ 5 U.S.C. § 552(a)(3)(A); *see also Wash. Post Co. v. U.S. Dep't of Health & Human Servs.*, 690 F.2d 252, 261 (D.C. Cir. 1982) (under Exemption 6, the presumption in favor of disclosure is as strong as can be found anywhere in the FOIA); *Cameranesi v. U.S. Dep't of Def.*, 856 F.3d 626, 637 (9th Cir. 2017) ("In order to withhold information from disclosure under Exemption 6, the agency must specifically invoke the exemption and must carry the burden of proving that disclosure would constitute a clearly unwarranted invasion of personal privacy.").

³⁴ National Ass'n of Home Builders v. Norton, 309 F.3d 26, 37 (D.C. Cir. 2002).

2. Exemption 5 is inapplicable.

The USDA cursorily asserted, with no explanation whatsoever, that "[r]esponsive records, if they existed, would be exempt from disclosure under Exemptions 5, 6, and/or 7C."³⁵ Exemption 5 is inapplicable to the requested inspection photographs. Exemption 5 protects from disclosure "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency."³⁶ Exemption 5 was intended to incorporate the government's common law privilege from discovery in litigation.³⁷

The Supreme Court of the United States has ruled that in order to qualify for protection under Exemption 5 the document's source "must be a government agency," and the document "must fall within the ambit of a privilege against discovery" recognized under Exemption 5.³⁸ The privileges recognized under Exemption 5 are: the deliberative process privilege,³⁹ the attorney work-product privilege,⁴⁰ the attorney-client privilege,⁴¹ confidential commercial information,⁴² statements from air crash investigations,⁴³ and reports of expert witnesses.⁴⁴ The records requested in the instant FOIA request were photographs that the USDA was required to take as part of their inspections of the non-AWA-compliant Pi Bioscientific facility—which clearly would not fit within any of the privileges recognized by Exemption 5, as these are purely factual documents, which could easily be segregated from any interagency or intra-agency memoranda.⁴⁵ Finally, as is discussed *infra*, even if it were to be determined that any portion of the records would, in fact, be protected from disclosure pursuant to Exemption 5, the records must still be segregated, and the non-protected portions released.⁴⁶

3. Exemptions 6 and 7(C) are inapplicable.

Exemption 6 protects from disclosure "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."⁴⁷ Exemption 7(C) protects from disclosure "records or information compiled for law enforcement purposes . . . [which] could be

³⁵ Ex. 1 at p. 2.

³⁶ 5 U.S.C. § 552(b)(5).

³⁷ H.R. Rep. No. 89-1497, at 10 (1966); S. Rep. No 89-813, at 29 (1965); S. Rep. No. 88-1219 at 6-7, 13-14 (1964).

³⁸ Dep't of Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8 (2001).

³⁹ NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150-54 (1975).

⁴⁰ *Fed. Trade Comm'n v. Grolier*, 462 U.S. 19 (1983).

⁴¹ Schlefer v. U.S., 702 F.2d 233, 245 (D.C. Cir. 1983).

⁴² Fed. Open Mkt. Comm. of the Fed. Reserve Sys v. Merrill, 443 U.S. 340, 360 (1979).

⁴³ United States v. Weber Aircraft Corp., 465 U.S. 792 (1984).

⁴⁴ *Hoover v. Dep't of Interior*, 611 F.2d 1132, 1138-42 (5th Cir. 1980).

⁴⁵ Envtl. Prot. Agency v. Mink, 410 U.S. 73, 87–89 (1973); see also Joseph Horne Co. v. N. L. R. B., 455 F. Supp. 1383, 1387 (W.D. Pa. 1978) ("[T]he photographic exhibits . . . are factual by their nature, are analogous to statements of witnesses, and are therefore not within Exemption 5").

⁴⁶ See segregability discussion *infra* at pp. 13-14.

⁴⁷ 5 U.S.C. § 552(b)(6).

expected to constitute an unwarranted invasion of personal privacy."⁴⁸ The responsive records in this case cannot be properly classified as a "personnel, medical, or similar file," or files collected for law enforcement purposes," nor would the records' disclosure constitute an "unwarranted invasion of personal privacy."

a. <u>The records requested do not constitute "personnel," "medical," or "similar</u> <u>files" or records "compiled for law enforcement purposes"</u>

The information within the records requested does not constitute "personnel," "medical," or "similar files" and therefore are not subject to Exemption 6.⁴⁹ The records PETA requested are USDA inspection photographs, which are agency records from inspections that are statutorily required for entities engaged in commercial enterprises that are regulated under the AWA.⁵⁰ The information within these records does not concern any aspect of the personal lives of anyone working within the facilities. Undoubtedly, these records could not be construed as constituting "personnel" or "medical" files.

Further, the information within the responsive records is not a "similar file" for the purposes of Exemption 6. Courts have held that records would be construed as "similar files" when they "implicate similar privacy values" as personnel and medical files.⁵¹ Inspection photographs do not provide any detailed personal information that would meet the threshold requirement of protection under Exemption 6 of the FOIA.⁵² Finally, Exemption 6 is not to be applied to prevent from disclosure the mere identity of individuals, even in cases in which release of this information may cause "embarrassment due to the nature of . . . work they have undertaken."⁵³

⁵¹ U.S. Dep't of Air Force v. Rose, 425 U.S. 352, 376-77 (1976).

⁴⁸ *Id.* § 552(b)(7)(C).

⁴⁹ See id. § 552(b)(6).

⁵⁰ See 7 U.S.C. § 2146(a) ("The Secretary shall make such investigations or inspections as he deems necessary to determine whether any dealer, exhibitor, intermediate handler, carrier, research facility, or operator of an auction sale subject to section 2142 of this title, has violated or is violating any provision of this chapter or any regulation or standard issued thereunder, and for such purposes, the Secretary shall, at all reasonable times, have access to the places of business and the facilities, animals, and those records required to be kept pursuant to section 2140 of this title of any such dealer, exhibitor, intermediate handler, carrier, research facility, or operator of an auction sale."); 9 C.F.R. § 2.3(a) (requiring exhibitors to make their "animals, premises, facilities, vehicles, equipment, other premises, and records available for inspection during business hours and at other times mutually agreeable to the applicant and APHIS, to ascertain the applicant's compliance with the standards and regulations").

⁵² See, e.g., Viacom Int'l, Inc. v. EPA, No. 95-2243, 1995 U.S. Dist. LEXIS 17469 (E.D. Pa. Nov. 17, 1995) (records of EPA soil testing, including names and addresses of persons residing where samples were collected, were not "similar files" because they were not detailed records about individuals).

⁵³ Sims v. Cent. Intelligence Agency, 642 F.2d 562, 575 (D.C. Cir. 1980) ("Exemption 6 cannot "be invoked . . . to protect the concerns of a contractor would be embarrassed by disclosure of his responsibility for shoddy work . . . [or] the names of those embarrassed by the nature of contract work they have undertaken."); see also Fuller v. C.I.A., No. CIV.A.04 253 RWR, 2007 WL 666586, at *4 (D.D.C. Feb. 28, 2007) (requiring disclosure of documents containing names because the names are in "connection with a professional or business relationship" and therefore "cannot fairly be characterized as personal information that exemption (b)(6) was meant to protect").

Research facilities are businesses operating under USDA regulation and inspection for the operations they have decided to undertake, i.e. conducting animal research. Accordingly, as the USDA itself has recognized, their business information is not entitled to the reasonable expectation of privacy that the FOIA's privacy exemptions affords to individuals outside of their business capacity.⁵⁴ "Information relating to business judgments and relationships does not qualify for exemption. This is so even if disclosure might tarnish someone's professional reputation."⁵⁵ The U.S. District Court of the District of Columbia has held that disclosure of addresses, where individuals' business and home addresses were the same "must be measured in light of the effect on [the individuals] as businesspeople."⁵⁶ The only information within the responsive records, in this case, that could possibly yield any information pertaining to individuals would be of their capacity as *businesspeople* at their business address.⁵⁷ Even in instances of requested information of a federal AWA licensee yielding the licensee's home address, which is not the case here, this would not, by itself, constitute an "unwarranted invasion of personal privacy" when the information relates to the licensee's business capacities.⁵⁸

Similarly, the information is not exempt from disclosure as records "compiled for law enforcement purposes." Again, the USDA provided no support at all in for its statement that the responsive records are protected from disclosure by Exemption 7(C).

Each piece of information for which the USDA invokes Exemption 7(C) must be "compiled for law enforcement purposes."⁵⁹ Mere possession of the records by an enforcement agency does not create an "enforcement purpose."⁶⁰ The D.C. Circuit focuses on whether the files relate to an actual "enforcement proceeding," as opposed to, for example, the agency engaging in its administrative inspection duties.⁶¹ Even if it turns out that the USDA did, or does, have an investigation with this facility—this investigation does not turn photos mandated to be taken during inspections to become records "compiled for law enforcement purposes." The information within the responsive records is clearly not the information that the FOIA's Exemptions 6 or 7(C) were designed to protect from disclosure, and thus the inspection report photographs would not be exempt from disclosure under these exemptions.

⁵⁴ See Brief of Appellee, Carolyn Jurewicz, Et Al., Appellants, v. U.S. Dep't of Agric., Appellee, and Humane Society of United States, Intervenor Appellee., 2013 WL 3804849 at 11 (D.C. Cir. July 22, 2013) (APHIS noting that "disclosure of the Licensees' business information here [as contained in AWA license renewal applications] weighs less heavily on the privacy side of the balance").

⁵⁵ Wash. Post Co. v. U.S. Dep't of Justice, 863 F.2d 96, 100 (D.C. Cir. 1988) (citing Cohen v. EPA, 575 F.Supp. 425, 429 (D.D.C. 1983)); see also Iowa Citizens for Cmty. Improvement v. U.S. Dep't of Agric., 256 F. Supp. 2d 946, 957 (S.D. Iowa 2002).

⁵⁶ Wash. Post Co. v. U.S. Dep't of Agric., 943 F. Supp. 31, 36 (D.D.C. 1996).

⁵⁷ See id.

⁵⁸ See id.

⁵⁹ 5 U.S.C. § 552(b)(7)(C); Fed. Bureau of Investigation v. Abramson, 456 U.S. 615, 622 (1982).

⁶⁰ See Simon v. U.S. Dep't of Justice, 752 Fed. Supp. 14, 17 (D.D.C. 1990) ("a document does not automatically meet FOIA's compiled-for-law-enforcement-purposes threshold merely by being in the FBI's possession").

⁶¹ Jefferson v. U.S. Dep't of Justice, Office of Professional Responsibility, 284 F.3d 172, 176-77 (D.C. Cir. 2002).

b. <u>Disclosure of the records would not constitute an unwarranted invasion of personal privacy.</u>

Exemption 6's "clearly unwarranted" standard places a heavy burden on the government, and as a result the presumption in favor of disclosure is strong.⁶² Furthermore, the District Court of the District of Columbia has observed that "[t]he privacy inquiries under Exemptions 6 and 7(C) are 'essentially the same."⁶³ Under both Exemptions 6 and 7(C), the third party must have more than a *de minimis* privacy interest that would be compromised by the release of the requested material.⁶⁴

Moreover, even if the USDA identifies segments of information within the responsive records as having a cognizable privacy interest to protect, it must still balance the privacy interest against the public's interest in disclosure.⁶⁵ Exemptions 6 and 7(C) require the court to "balance the right of privacy of affected individuals against the right of the public to be informed⁶⁶ Courts undertake a four-step analysis to determine whether information is protected from disclosure under Exemption 6.⁶⁷ First, as noted above, the agency or court must determine whether each document is a personnel, medical or "similar" file.⁶⁸ Second, the agency or court must determine if the individuals identified in the documents have a significant, as opposed to *de minimis*, privacy interest in the requested information.⁶⁹ Third, the agency or court must evaluate the strength of the public's interest in disclosure.⁷⁰ Finally, the agency and court must balance the individual's privacy interest with the public's interest in disclosure and determine whether disclosure would constitute a clearly unwarranted invasion of personal privacy.⁷¹

The USDA failed to provide *any* substantive discussion regarding the records being protected from disclosure under Exemptions 6 or 7C, including any substantive balancing analysis.

The responsive records do not implicate privacy interests that are protected under the FOIA. First, it is not at all clear what information within the records would, in any way, be personally identifying. The records requested in this matter are photographs of AWA violations, which are required to be taken.

⁶² Morley v. C.I.A., 508 F.3d 1108, 1127-28 (D.C. Cir. 2007).

⁶³ Judicial Watch, Inc. v. U.S. Dep't of Homeland Sec., 598 F.Supp.2d 93, 96 n.1 (D.D.C. 2009).

⁶⁴ Citizens for Responsibility & Ethics in Wash. v. U.S. Dep't of Justice, No. 11-754(GK), 2012 WL 45499 at *4 (D.D.C. Jan. 10, 2012); Am. Civil Liberties Union v. U.S. Dep't of Justice, 655 F.3d 1, 12 (D.C. Cir. 2011); AquAlliance v. U.S. Bureau of Reclamation, 139 F. Supp. 3d 203, 208-09 (D.D.C. 2015).

⁶⁵ See, e.g., Schiffer v. FBI, 78 F.3d 1405, 1410 (9th Cir. 1996) (explaining that in Exemption 7(C) context, once agency shows that privacy interest exists, court must balance it against public's interest in disclosure).

⁶⁶ Getman v. N.L.R.B., 450 F.2d 670, 674 (D.C. Cir. 1970); see also Albuquerque Publ'g Co. v. U.S. Dep't of Justice, 726 F. Supp. 851, 855 (D.D.C. 1989).

⁶⁷ See, e.g., Aqualliance v. U.S. Army Corps of Eng'rs, 243 F. Supp. 3d 193, 197 (D.D.C. 2017). ⁶⁸ Id. at 197.

⁶⁹ *Id.*; *Judicial Watch, Inc. v. U.S. Dep't of State*, 875 F. Supp. 2d 37, 46 (D.D.C. 2012).

⁷⁰ *Aqualliance*, 243 F. Supp. 3d at 197.

 $^{^{71}}$ *Id*.

These photographs documenting AWA violations would be of animals, facilities, and possibly of records that do not comply with the AWA's record requirements—but would not include people.⁷² Additionally, on the off chance that any photograph did include a person's face or personally-identifiable information, this information could easily be blurred out by the agency and be released appropriately.

Moreover, even if a cognizable privacy interest were shown to exist, disclosure of personally-identifying information is not always "clearly unwarranted"; whether such disclosure "is a significant or *de minimis* threat depends on the characteristic(s) revealed . . . and the consequences likely to ensue."⁷³ The only information of individuals that would possibly be provided in the responsive records would exclusively be in their capacity as businesspeople working at their place of business. It is insufficient under the FOIA for the agency to simply assert, in a vague and conclusory fashion, that the redacted information will lead to harassment.⁷⁴ It is unlikely that there would be any actual reasonably foreseeable likelihood of embarrassment or harassment from the release of the responsive records—but even if there were, a threat to someone's professional reputation is not a valid privacy interest.⁷⁵ Furthermore, the licensee in this matter is a corporation that does not have privacy interests protected under the FOIA.⁷⁶

In the event that any of the photographic records would be of records maintained by Pi Bioscientific, especially in light of the IACUC citations Pi Bioscientific received,⁷⁷ the USDA inspector was required to allow the facility the "opportunity to redact names, locations and other PII before taking photos, scanning, or making copies of the record," and to allow the facility the "opportunity to view [the] photos" and wherever possible the inspector should "delete or retake any photos that the facility states may contain potential PII, or confidential or proprietary information to remove or block the sensitive information."⁷⁸ Accordingly, if any of these types of records exist, Pi Bioscientific has already been given the opportunity to redact, among other things, any of the information that contained any personally-identifiable information—and thus, the release of these records could not now be construed as an unwarranted invasion of personal privacy.

Consequently, the information within the responsive records is not the sort of information FOIA Exemptions 6 or 7(C) were designed to protect, nor is it information in which there would be reasonable

⁷² United States Department of Agriculture Animal Welfare Inspection Guide (2017), Required Inspection Procedures, Inspection Photographs 2-15,

 $https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf.$

⁷³ U.S. Dep't of State v. Ray, 502 U.S. 164, 176, n.12 (1991) (internal quotation marks and citation omitted).

⁷⁴ See Hall v. U.S. Dep't of Justice, 552 F. Supp. 2d 23 (D.D.C. 2008).

⁷⁵ See In Defense of Animals v. Nat'l Insts. of Health, 543 F. Supp. 2d 83 (D.D.C. 2008); see also Wash. *Post Co. v. Dep't of Justice*, 863 F.2d at 100 (a threat to someone's professional reputation is not a valid privacy interest).

⁷⁶ See FCC v. AT&T, 562 U.S. at 409-10.

⁷⁷ Ex. 3.

⁷⁸ United States Department of Agriculture Animal Welfare Inspection Guide (2017), Research Facility Inspection – IACUC Requirements and Protocols, 7-49 – 7-50.

 $https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf.$

expectation of privacy, and thus there is little to no privacy interest in any of the information in the responsive records.

The public's interest in the responsive records, however, is very strong. As Senator Dole explained in sponsoring critical amendments intended to strengthen protections for animals at research facilities like Pi Bioscientific, the AWA aims "to ensure the public that adequate safeguards are in place to prevent unnecessary abuses to animals, and that everything possible is being done to decrease the pain of animals during experimentation and testing."⁷⁹ The en banc U.S. Court of Appeals for the D.C. Circuit recognized nearly two (2) decades ago that "the AWA anticipated the continued monitoring of concerned animal lovers to ensure the purposes of the Act were honored."⁸⁰ Congress "encouraged the continued monitoring of humane societies and their members. They spoke, for instance, of how America had long depended on humane societies to bring the mistreatment of animals to light."⁸¹ When the AWA was passed in the mid-sixties, Congress received more mail about animal welfare than civil rights and the Vietnam War combined.⁸²

To further the public's substantial interest in ensuring proper implementation of the AWA by the USDA, the public's ability to receive APHIS' records pertaining to entities that are regulated under the Act is of critical importance.⁸³ This is especially true in cases involving a persistently non-AWA-compliant facility such as Pi Bioscientific—which has routinely been cited by the USDA for its failure to comply with the minimum requirement of the AWA, including for failing to provide proper animal housing, improper storage of animal food, unsanitary living conditions for animals, non-compliance with Institutional Animal Care and Use Committee ("IACUC") procedures, and non-compliance with the proper attending veterinarian and adequate veterinary care procedures.⁸⁴ In addition to the twenty violations Pi Bioscientific was cited for over just six days in March 2016, the facility was cited just last month for four violations, including yet two more repeat violations—one of them yet another direct veterinary care violation, for failing adequately care for eight suffering animals.⁸⁵

The public's interest in this information is especially high given the USDA's own Office of the Inspector General ("OIG") issuing numerous audits over the past couple of decades condemning the agency's enforcement of the AWA.⁸⁶ Moreover, the USDA has repeatedly recertified Pi Bioscientific's AWA certificate despite chronic violations, another issue of great public interest that the OIG has previously

⁷⁹ 131 Cong. Rec. 29,155 (1985) (statement of Sen. Dole).

⁸⁰ Animal Legal Def. Fund, Inc. v. Glickman, 154 F.3d 426, 445 (D.C. Cir. 1998).

⁸¹ Id. (citing 116 Cong. Rec. 40,305 (1970) (statement of Rep. Whitehurst)).

⁸² U.S. Dep't of Agric., Animal Welfare Act 1966-1996: Historical Perspectives and Future Directions, vii (1996), <u>https://archive.org/stream/CAT10860535/CAT10860535_djvu.txt</u>.

 ⁸³ Jurewicz v. U.S. Dep't. of Agric., 891 F. Supp. 2d 147, 159 (D.D.C. 2012), aff'd, 741 F.3d 1326 (D.C. Cir. 2014) (holding that assessing the accuracy of USDA inspections was of legitimate public interest).
 ⁸⁴ Ex. 3.

⁸⁵ Id.

⁸⁶ USDA, OIG, APHIS Oversight of Research Facilities, Audit No. 33601-0001-41, p. 2 of pdf (Dec. 2014), https://www.usda.gov/oig/webdocs/33601-0001-41.pdf (summarizing series of audits).

flagged.⁸⁷ Just last year, the OIG issued an audit specifically raising concerns about AWA inspections, finding that "[i]nspections are not always uniformly completed or adequately documented because of insufficient guidance; this reduces assurance that those exhibitors are in compliance with the AWA."⁸⁸ Access to the inspection photographs at issue here is important to allow oversight of USDA's inspection process under the AWA, including whether the agency is adequately documenting inspections in accordance with the mandates of its own inspection guide, including the requirements for photographing certain violations discussed above.⁸⁹ Indeed, the OIG has previously found that some AWA inspectors "did not always adequately . . . support violations with photos."⁹⁰ The OIG found that this failing put animals at "higher risk for neglect or ill-treatment"—in contravention of the purposes of the AWA—and weakened enforcement actions.⁹¹ The OIG further noted that this failing made identification of animals in need of care on reinspection (and thus whether the facility has come into compliance) difficult.⁹² In response, APHIS management acknowledged a potential need for additional training in collecting evidence.⁹³

As APHIS itself has previously recognized in the AWA context—and as the D.C. Circuit has affirmed a substantial public interest served by disclosure is "help[ing] the public gauge the effectiveness of USDA inspections."⁹⁴ The public's interest in ensuring the USDA's meaningful oversight of the facility under the AWA is substantial and clearly outweighs any minimal privacy interests that may be identified.⁹⁵ Accordingly, the responsive records are not be exempt from disclosure pursuant to Exemptions 6 or 7(C), and must be provided in full.

⁸⁷ USDA, OIG, Audit Report No. 33002-0001-Ch, Animal and Plant Health Service Implementation of the Animal Welfare Act (1992); *see also* USDA, OIG, Audit Report No. 33600-1-Ch, Animal and Plant Inspection Service, Enforcement of the Animal Welfare Act (1995).

⁸⁸ USDA, OIG, APHIS: Animal Welfare Act – Marine Mammals (Cetaceans), Audit No. 33601-0001-31, p. 2 of pdf (May 2017). Although focused on facilities with cetaceans, the audits findings are highly relevant to USDA's oversight of *all* types of facilities regulated under the AWA.

⁸⁹ See id. at 9 ("Without uniform inspections and documentation of what was reviewed, APHIS may not be able to provide assurance that those . . . subject to inspection are in compliance with the AWA.").

⁹⁰ USDA, OIG, Animal and Plant Health Inspection Service Animal Care Program Inspections of Problematic Dealers, Audit No. 33002-4-SF, at 2, <u>https://www.usda.gov/oig/webdocs/33002-4-SF.pdf</u>; *accord id.* at 17; *see also id.* at 22 ("We found that photos were not always taken when necessary, even though APHIS issues digital cameras to the inspectors as part of their field equipment.").

⁹¹ *Id.* at 17; *see also id.* at 22 (finding that in 7 of 16 enforcement decision reviewed, violations had been dismissed for lack of insufficient evidence, including photographs).

 $^{^{92}}$ *Id.* at 19.

 $^{^{93}}$ *Id.* at 17.

⁹⁴ Jurewicz v. U.S. Dep't. of Agric., 891 F. Supp. 2d 147, 157 (D.D.C. 2012), aff'd, 741 F.3d 1326 (D.C. Cir. 2014).

⁹⁵ See, e.g., Wash. Post Co. v. U.S. Dep't of Agric., 943 F. Supp. at 36 (finding disclosure of information regarding recipients of federal subsidies under cotton subsidy program would further significant public interest in shedding light on the workings of USDA in administration of its massive subsidy program).

D. The USDA may not give an "across-the-board" Glomar response.

Even if portions of the Pi Bioscientific records contained information for which a Glomar response was proper, the agency must still provide records are *not* protected by one of FOIA exemptions. "Across-the-board" Glomar responses are unjustified where there are records that fall outside of FOIA's exemptions.⁹⁶ Consequently, even if it were to be determined that portions of the responsive records could be protected from disclosure due to an exemption of the FOIA—and acknowledgement of the existence of these records would itself cause harm cognizable under the exemption—the reasonably segregable portions of the records that *would not* be protected by a privacy exemption must be provided.

The FOIA requires agencies to take "reasonable steps necessary" to segregate and release non-exempt information.⁹⁷ Since FOIA's focus is "information, not documents," an agency "cannot justify withholding an entire document simply by showing that it contains some exempt material."⁹⁸ "In addition to establishing that information is properly withheld under the claimed FOIA exemption, an agency seeking to withhold information bears the burden of establishing that all reasonably segregable non-exempt portions of records are disclosed."⁹⁹ Claims of non-segregability must be made with the same degree of detail as required for claims of exemption.¹⁰⁰

As the Department of Justice has long recognized, "The clear purpose of this statutory requirement . . . is to 'prevent the withholding of entire [documents] merely because portions of them are exempt, and to require the release of nonexempt portions."¹⁰¹ And yet withholding entire documents is *precisely* what the USDA did in this case, in total contravention of the law. As the Department of Justice's Office of Information policy has emphasized, "In administering the [FOIA] . . . agencies must not overlook their obligation to focus on individual record portions that require disclosure. This focus is essential in order to meet the Act's primary objective of 'maximum responsible disclosure of government information."¹⁰²

⁹⁶ PETA v. Nat'I Inst. Health, 745 F.3d 535, 541 (D.C. Cir. 2014).

 $^{^{97}}$ 5 U.S.C. § 552(a)(8)(A)(ii)(II); *see also* 5 U.S.C. § 552(b) ("Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt"); 7 C.F.R. § 1.15(b) ("In the event a requested record contains some portions that are exempt from mandatory disclosure and others that are not, the official responding to the request shall ensure that all reasonably segregable nonexempt portions are disclosed").

⁹⁸ *Clemente*, 64 F. Supp. 3d at 116 (quoting *Krikorian v. U.S. Dep't of State*, 984 F.2d 461, 467 (D.C. Cir. 1993)).

⁹⁹ In Def. of Animals v. U.S. Dep't of Agric., 656 F. Supp. 2d 68, 73, 82 (D.D.C. 2009) (holding that the Department of Agriculture failed to meet its burden of demonstrating that all reasonably segregable nonexempt information from 1017 withheld pages had been disclosed).

¹⁰⁰ See, e.g., Mead Data Central, 566 F.2d at 261-62; Sciacca v. F.B.I., 23 F. Supp. 3d 17, 26 (D.D.C. 2014) (agency "must provide a detailed justification and not just conclusory statements to demonstrate that all reasonably segregable information has been released" (internal quotation marks and citations omitted)).

 ¹⁰¹ Department of Justice, Office of Information Policy, FOIA Update Vol. XIV, No. 3, OIP Guidance: The 'Reasonable Segregation' Obligation (Jan. 1, 1993) (quoting Attorney General's Memorandum on the 1974 Amendments to the Freedom of Information Act 14 (Feb. 1975)) (alteration in original).
 ¹⁰² Id. (citation omitted).

II. The USDA Unlawfully Redacted Inspection Photographs for Research Facility Robert Sargeant.

A. <u>The USDA Has Not Met Its Burden of Demonstrating That the Withheld</u> <u>Information Is Exempt from Disclosure Under Exemption 6 or Exemption 7(C).</u>

As mentioned above, the eight (8) pages provided by the USDA in response to the portion of the request asking for the photographs in the USDA's possession in March of 2016 for the inspection site affiliated with Robert Sargeant (Certificate Number: 93-R-0283, Customer Number: 1115) are attached as Exhibit 2. The photographs themselves, as well as their descriptions and the dates on which they were taken, are completely redacted pursuant to Exemption 6 and 7(C) of the FOIA. Similar to the Pi Bioscientific photographic records, discussed *supra*, the photographic records for the facility affiliated with Sargeant do not contain private information that is protected by the FOIA.

In completely redacting these records, the USDA stated:

[W]e are withholding the identifying information of private individuals' name and job title.

We have determined that the confidential source has more than a *de minimis* privacy interest in this information because the identifying information could be used to make unwanted contact or communications with individuals mentioned in the documents. . . . We determined that the release of the identifying information does not shed any light on APHIS activities. Therefore, the privacy interests of the individuals in the records you have requested outweigh the non-existent public interest in disclosure of the information.¹⁰³

Although the USDA indicated that it was only withholding information that identified individuals' names and job titles, it clearly redacted much more than this: Review of the heavily redacted records provided to PETA shows that all eight (8) inspection photographs were completely redacted, along with the descriptions of all photographs and the dates of these photographs.¹⁰⁴

The USDA provided no explanation whatsoever for withholding the information pursuant to Exemption 7C. As discussed above, the USDA cannot meet the FOIA's requirements by merely reciting an exemption's statutory language, but instead must adequately *explain* the reasoning and justification for the withholding. This was not done with the records provided for the facility affiliated with Sargeant, and the thus the USDA has failed to undergo the proper procedures in redacting these records.

Additionally, these inspections photographs are not protected from disclosure under Exemption 6 or 7C. Like the Pi Bioscientific records discussed *supra*, the Sargeant photographic records are not "personnel," "medical" or "similar files"; nor were they "compiled for law enforcement purposes."¹⁰⁵

Furthermore, disclosure of the requested photographic records would not constitute an invasion of personal privacy. Like the Pi Bioscientific photographs discussed *supra*, the Sargeant photographs do

¹⁰³ Ex. 1 at 2.

¹⁰⁴ *See* Ex. 2.

¹⁰⁵ See Discussion of Exemptions 6 and 7(C) supra at pp. 7-13.

not contain private information that is protected under either Exemption 6 or 7C, and in the limited instances where photographs of records may have been taken, the facility has already been given the opportunity to redact any personally-identifiable information.¹⁰⁶ Moreover, the public interest in receiving the inspection records for this facility is very strong. The March 17, 2016, USDA Inspection Report cited the facility for IACUC procedural violations, animal safety violations in the indoor facilities rabbits were being kept in, and several instances of unsanitary conditions including containing: dried fecal matter, food/waste material, and decomposing organic/waste material.¹⁰⁷ The public's interest in ensuring the USDA's meaningful oversight of the facility under the AWA is substantial and clearly outweighs any minimal privacy interests that may be identified. Accordingly, the responsive records would not be exempt from disclosure pursuant to Exemptions 6 or 7(C), and should be provided in full.

B. The USDA Failed to Meet Its Burden of Demonstrating That It Disclosed All "Reasonably Segregable" Portions of the Requested Records.

As discussed above, if portions of the responsive records are found to be protected from disclosure pursuant to an exemption of the FOIA, the FOIA still requires agencies to take the reasonable steps necessary to segregate and release the non-exempt information.¹⁰⁸

Courts have specifically held that in applying both Exemptions 6 and 7(C), agencies are required to release all remaining information after limiting any redactions to only those that must be made to protect individual privacy interests.¹⁰⁹ In this case, all eight (8) of the pages of responsive records pertaining to the facility affiliated with Sargeant were withheld in their entireties,¹¹⁰ with the only explanation (for Exemption 6) merely being that "we are withholding the identifying information of private individuals' name and job title," and no explanation for Exemption 7(C).¹¹¹ The records requested, however, were of photographs the USDA inspectors were mandated to take for cited AWA violations—and thus clearly the redactions went well beyond merely withholding "private individuals' name and job title." Indeed, it is not even clear how private individual's name and job title would appear in the photographic records requested, as this information would not appear to be part of the request. Furthermore, the citations specified within the March 17, 2016 USDA Inspection report do not pertain to individuals, but instead involve AWA violations of the facility and the facility's records.¹¹²

¹⁰⁶ *Id*.

¹⁰⁷ Ex. 4.

¹⁰⁸ See segregability discussion supra at p. 14.

¹⁰⁹ See, e.g., Canning v. Dep't of Justice, No. 01-2215, slip op. at 19 (D.D.C. Mar. 9, 2004) (finding application of Exemption 7(C) to entire documents rather than to personally-identifying information within documents to be overly broad); *Church of Scientology Int'l v. Dep't of Justice*, 30 F.3d 224, 230-31 (1st Cir. 1994) (deciding that Vaughn Index must explain why documents entirely withheld under Exemption 7(C) could not have been released with identifying information redacted); *Lawyer's Comm. for Civil Rights v. U.S. Dep't of the Treasury*, No. 07-2590, 2008 WL 4482855, at *21 (N.D. Cal. Sept. 30, 2008) (requiring parties to meet and confer regarding scope of Exemption 6 and 7(C) redactions to ensure only private information is withheld and alleviate need for Vaughn Index).

¹¹⁰ Ex. 2.

¹¹¹ Ex. 1 at p. 2.

¹¹² Ex. 4.

Accordingly, with the USDA providing no substantive discussion for its overly broad application of the FOIA exemptions beyond merely providing general and conclusory language, it is impossible to conclude that the records have been properly or improperly redacted. However, as discussed above, since much, if not all, of the redacted information poses no risk of yielding an unwarranted invasion of privacy, these sweeping redactions are at least partially—and perhaps completely—misapplied. Assuming that portions of the requested documents may be withheld, the reasonably segregable portions of these records must still be provided and any remaining redactions fully justified.

III. The USDA Has Not Adequately Explained Its Change in Policy.

AWA inspection photographs have routinely been provided by the USDA in response to FOIA requests as a long-established policy. In this case the USDA has asserted a Glomar response and the application of Exemptions 6 and 7(C) to information to which the agency has consistently provided—and accordingly the USDA has not provided a "detailed justification" for its decision to change its long-established policy in, now, deciding to assert a Glomar response and FOIA exemptions in this manner.¹¹³

When an agency changes a policy or legal interpretation, it must provide a "reasoned explanation," "display awareness that it *is* changing position," and explain why it believes the new interpretation is better than its previous interpretation.¹¹⁴ Otherwise, the agency has acted arbitrarily and capriciously.¹¹⁵ Further, an agency's interpretation of a relevant provision that conflicts with its earlier interpretation is "entitled to considerably less deference" than a consistently held agency view.¹¹⁶

For the reasons discussed above, the USDA must either release the requested information in full, or reasonably segregate any exempt information from nonexempt information. I look forward to your response within 20 business days of receipt of this timely filed administrative appeal.¹¹⁷

¹¹³ See, e.g., Greenpeace v. Nat'l Marine Fisheries Serv., 198 F.R.D. 540, 543 (W.D. Wash. 2000) (citation omitted).

¹¹⁴ FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009).

¹¹⁵ Organized Vill. of Kake v. U.S. Dep't of Agric., 746 F.3d 970, 974-75 (9th Cir. 2014) (citing Fox, 556 U.S. at 515-16).

¹¹⁶ Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 515 (1994) (quoting INS v. Cardoza-Fonseca, 480 U.S. 421, 447 (1987)).

¹¹⁷ See 5 U.S.C. § 552(6)(A)(ii); 7 C.F.R. § 1.14(c).

Very truly yours,

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Storm Estep, Ésq. Counsel 1536 16th St. NW Washington, DC 20036 202-540-2198 | Office 202-540-2208 | Facsimile StormE@petaf.org

EXHIBIT 1



Animal and Plant Health Inspection Service

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Legislative and Public Affairs

Freedom of Information

4700 River Road Unit 50 Riverdale, MD 20737-1232 January 16, 2018

Katherine Groff Via email: <u>katherineg@peta.org</u>

Dear Ms. Groff:

This letter is in response to your February 9, 2017, Freedom of Information Act (FOIA) request for the following information:

 <u>Customer Number</u>: 1115 <u>Certificate Number</u>: 93-R-0283 <u>Inspection Site Name</u>: Robert Sargent <u>Request</u>: All photographs taken by the USDA at the facility or otherwise in USDA's possession from March 2016.
 <u>Customer Number</u>: 331329

<u>Certificate Number</u>: 91-R-0072 <u>Inspection Site Name</u>: Pi Bioscientific Inc. - Site 001 <u>Request</u>: All photographs taken by the USDA at the facility or otherwise in USDA's possession from March 2016.

- <u>Customer Number</u>: 43309
 <u>Certificate Number</u>: 93-R-0521
 <u>Inspection Site Name</u>: Pro Sci Inc. Site 002
 <u>Request</u>: All photographs taken by the USDA at the facility or otherwise in USDA's possession from July 2015, March 2016, and September 2016.
- 4) <u>Customer Number</u>: 43309 <u>Certificate Number</u>: 93-R-00229 <u>Inspection Site Name</u>: Pro Sci Inc. - Site 001 <u>Request</u>: All photographs taken by the USDA at the facility or otherwise in USDA's possession from March 2016 and September 2016.

Your request was received in this office on February 9, 2017, and assigned case number FOIA 2017-APHIS-02031-F.

On February 26, 2017, your request was forwarded to the Animal Care (AC) program office to conduct a search for records responsive to your request. On August 24, 2017, AC completed the search of their Animal Care Information System (ACIS) electronic filing database using the information provided in your request. AC located 72 pages of records responsive to your request. Of these 72 pages, 8 pages are responsive to Certificate Number 93-R-0283 and are being withheld in part pursuant to FOIA Exemption 6, 5 U.S.C. § 552 (b)(6) and FOIA Exemption 7, 5 U.S.C. § 552 (b)(7)(c). Additionally, the the 64 pages responsive to Customer Number 43309 are being released to you in their entirety without any redactions.

Exemption 6

Exemption 6 permits the government to withhold from "personnel and medical files and similar files" information about individuals when the disclosure of such information "would constitute a clearly unwarranted invasion of personal privacy." We have determined that these records meet the definition of "similar" files, because they contain information pertaining to individuals.

In order to determine whether a document may be withheld under Exemption 6, an agency must undertake a three-step analysis. First, the agency must determine whether a significant privacy interest would be compromised by the disclosure of the record. Second, the agency must determine whether the release of the document would further the public interest by shedding light on the operations and activities of the Government. Third, the agency must balance the identified privacy interests against the public interest in disclosure. In this circumstance, we are withholding the identifying information of private individuals' name and job title.

We have determined that the confidential source has more than a *de minimis* privacy interest in this information because the identifying information could be used to make unwanted contact or communications with individuals mentioned in the documents. Under Exemption 6, the only pertinent public interest is whether release of the information would shed light on the agency's activities and the agency's performance of its statutory duties. We determined that the release of the identifying information does not shed any light on APHIS activities. Therefore, the privacy interests of the individuals in the records you have requested outweigh the non-existent public interest in disclosure of the information.

Finally, regarding AC's search for responsive documents Certificate Number 91-R-0072 in your request, I can neither confirm nor deny that any records exist. AC conducted a search for records related to your request during the timeframe you specified. Confirmation of the existence of such records would itself reveal exempt information. To acknowledge the existence of records would constitute a clearly unwarranted invasion of personal privacy pursuant to Exemption 6 of the FOIA. Responsive records, if they existed, would be exempt from disclosure under Exemptions 5, 6, and/or 7C.

Because of the obvious possibility of embarrassment, harassment, intimidation, or other personal intrusions, we find that to even acknowledge that responsive records may exist pertaining to any portion of your request would result in a substantial invasion of privacy. While APHIS is strongly committed to keeping the public fully informed about agency operations, we also are concerned about preserving the privacy rights of individuals. An agency's statement in response to a FOIA request, that it can neither confirm nor deny the existence of records, is commonly called a "Glomar" response. A Glomar response is justified when confirmation of the existence of certain records would itself reveal exempt information and the following four circumstances exist:

- 1. The request is made by a third party.
- 2. The request is for information about a person identified by name.
- 3. The named individual is not deceased.
- 4. The individual has not given the requester a waiver of his privacy right.

I have determined that all of the above circumstances exist, and therefore, a Glomar response is justified for Item #2 of your request.

You may contact Kacie Edwards, the analyst who processed your request, at (301) 851-4084 or Kacie.L.Edwards@aphis.usda.gov as well as Mr. James Ivy, our FOIA Public Liaison, at (301) 851-4100 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to: Administrator, Animal and Plant Health Inspection Service, Ag Box 3401, Washington, DC 20250-3401. Your appeal must be postmarked or electronically transmitted within 90 days of the date of the response to your request.

Please refer to FOIA 2016-APHIS-02031-F in your appeal letter and add the words "FOIA Appeal" to the front of the envelope. To assist the Administrator in reviewing your appeal, provide specific reasons why you believe modification of the determination is warranted.

Because the cost to process your request is less than \$25.00, the fee has been waived.

Sincerely,

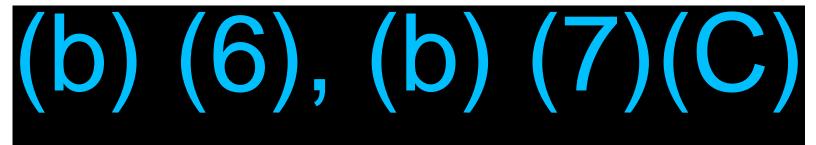
LAZ

For Tonya Woods Director Freedom of Information and Privacy Act

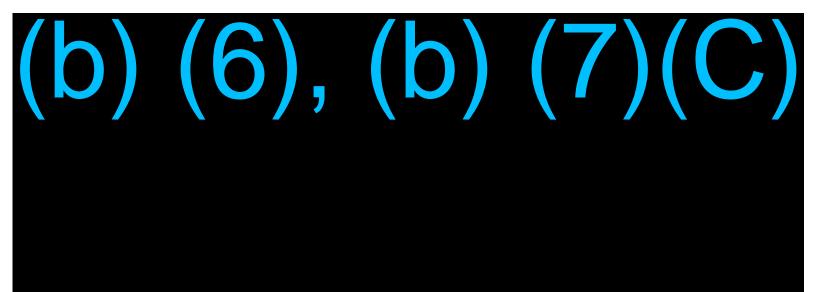
Legislative and Public Affairs

Enclosures

EXHIBIT 2



Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C) _, '16	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		
	FOIA	2017-APHIS-02031-F 000001	



Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C) '16	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		
		FOIA 2017-APHIS-02031-F_000002	

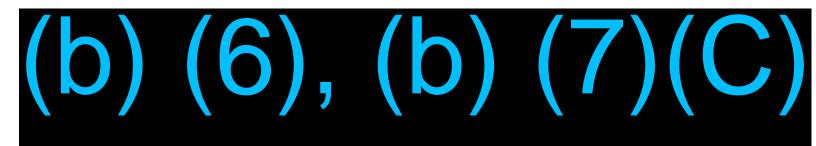
Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C), '16	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		
	-	OIA 2017-APHIS-02031-F 000003	

Photographer:		Legal Name:	93-R-0283
Photo Taken:	b) (6), (b) (7)(C), '16	ROBERT SARGEANT	
Inspection:	b) (6), (b) (7)(C)		
Description:	b) (6), (b) (7)(C)	017-APHIS-02031-F 000004	

Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C) <mark>, '1</mark> 6	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		
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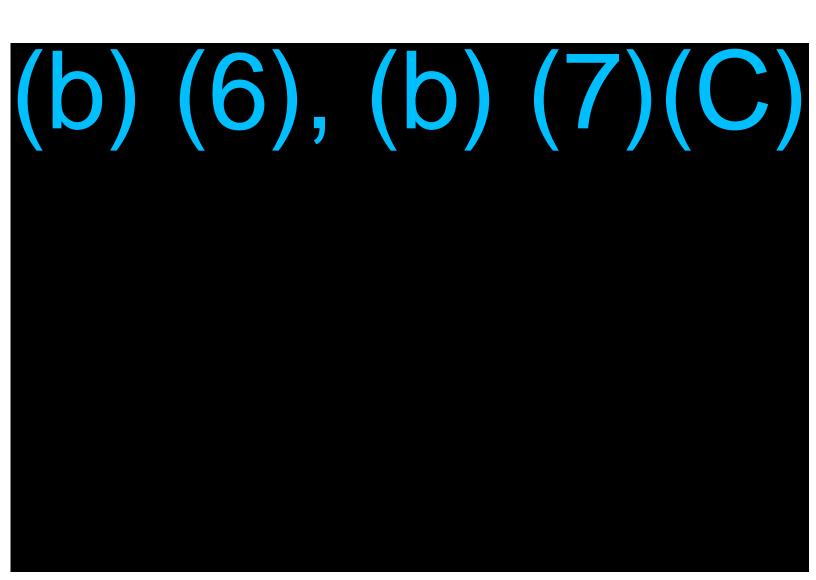
Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C), '16	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		
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FOIA 2017-APHIS-02031-F_000006



Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C), '16	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		

FOIA 2017-APHIS-02031-F_000007



Photographer:		Legal Name:	93-R-0283
Photo Taken:	(b) (6), (b) (7)(C) _, '16	ROBERT SARGEANT	
Inspection:	(b) (6), (b) (7)(C)		
Description:	(b) (6), (b) (7)(C)		

FOIA 2017-APHIS-02031-F_000008

EXHIBIT 3



Inspection Report

Pi Bioscientific Inc. 8315 Lake City Way N E Seattle, WA 98118

Customer ID: 331329 Certificate: 91-R-0072 Site: 001 Pi Bioscientific Inc.

> Type: ROUTINE INSPECTION Date: Mar-03-2016

2.33 (a) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The attending veterinarian has not been given the appropriate authority by the research facility to ensure that adequate veterinary care is provided to the animals. The attending veterinarian's instructions on animal care to include the use of deworming medications have not been followed. In addition, instructions on disease prevention to include biosecurity and the separation of newly acquired animals have not been followed. The attending veterinarian also advised the facility to have three animal care staff to facilitate appropriate care. Finally, the attending veterinarian has not recently visited the facility in order to oversee the adequacy of all other aspects of animal care and use. Without appropriate authority for the attending veterinarian, animal care and disease prevention is compromised leading to significant animal health issues and undue pain and suffering.

To be corrected by: immediately

2.33 (a) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The attending veterinarian is not a voting member of the IACUC. And although the IACUC has a veterinarian on the committee, he is not affiliated with the research facility. The attending veterinarian's function on the committee is to provide expertise in the care and use of the animals. The input of the attending veterinarian is critical to prevent inappropriate procedures and to ensure that any pain, distress or discomfort to the animals is avoided or minimized.

To be corrected by: April 8, 2016

2.33 (b) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Based on the numerous medical ailments and severe health issues observed in the goats on this inspection, the research facility does not have an adequate number of staff to provide care for the animals. In addition, based on the extremely poor state of sanitation of the goat/sheep barn and the repairs

Prepared By:	DIANE FORBES, D.V.M.		
, ,	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:	
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Received By:	(b)(6),(b)(7)(c)	Date:	
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Inspection Report Explanation: http://www.aphis.usda.gov/animal_welfare/downloads/IR_Explanation.pdf



Inspection Report

needed for barn and the outdoor shelters in the pasture, the research facility does not have adequate staffing for cleaning and maintenance. The facility also lacks bedding for the animals and the appropriate equipment to remove the manure of 46 animals. Although the facility has a power washer, someone had come and taken it to use at a facility elsewhere when the staff wanted to used it to clean the restraint and bleeding area. Equipment for cleaning and disinfection must be available at all times. Finally, the facility lacks a separate enclosure to house ill animals to facilitate their care and prevent the spread of disease.

Lack of adequate staffing, equipment, and facilities has adversely affected the care and well-being of the animals, prevented proper biosecurity, and has led to severe discomfort and pain and suffering in these animals.

To be corrected by: April 8, 2016

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Non-Direct NCI Expired medications were found in the refrigerator during the inspection. These included a bottle of Panacur (expiration 11-2015) and a bottle of Cydectin (expiration 3-2015).

Expired medications should not be used in the treatment of regulated animals as they may have lost potency or do not function as intended. It is the responsibility of the IACUC to ensure that the methods utilized in the prevention and treatment of diseases or injuries are in accordance with established standard veterinary practices.

To be corrected by: March 18, 2016

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Non-Direct NCI The research facility must perform daily observations of all animals to assess their health and well-being. According to the USDA inspection conducted on 9/10/14, the animal inventory indicated the facility had 60 goats and 5 sheep. For the USDA inspection on 11/20/14, the animal inventory showed the facility had 43 goats and 5 sheep. Based on the facility records for 02/13/15, they had 46 goats and 5 sheep. On today's inspection, they had 42 goats and 4 sheep. The facility cannot account for the animals that are missing nor explain the discrepancy in the number of animals.

The facility must perform daily observations which includes keeping track of the animals and what happens to them, and have the documentation available for review by APHIS officials. In addition, a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and wellbeing is conveyed to the attending veterinarian.

To be corrected by: March 18, 2016

Prepared By:	DIANE FORBES, D.V.M.	
	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFICER Inspector 5053	Mar-14-2016
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Inspection Report Explanation: http://www.aphis.usda.gov/animal_welfare/downloads/IR_Explanation.pdf



Inspection Report

3.125 (a)

FACILITIES, GENERAL.

**The goat/sheep barn is a very large structure divided into several different areas: sleeping, hay feeding, and grain feeding areas. The barn had a large sliding door on the south side that is now missing. There are also broken and missing boards, and boards with holes along the sides of the structure. This has allowed rain and wind to enter the facility contributing to the extremely wet conditions within the barn. In addition, the concrete walkway on the north side of barn slopes sharply towards the structure, so that as it rains the water runs down the walkway directly into the hay feeding area for the animals. The adjacent barn north of the goat/sheep barn functions as a fence for the walkway, and it has broken and damaged boards. There is also a support pole in the sleeping area of the barn that has a metal wrap around at the base that is rusted.

**The roof of the goat/sheep barn is composed of metal panels. The panels on the eastern side of the roof are rusted away allowing precipitation to fall inside of the barn below, thus soaking the feeding and sleeping areas for the animals.

Poor maintenance of the goat/sheep barn has resulted in extremely wet conditions inside the structure. This has contributed to the numerous and severe health issues seen in the goats, and resulted in pain and discomfort for these animals.

**The outdoor shelters have boards that have fallen from the structures and are lying on the ground. There is also a broken picnic table next to one of the shelters that is now just loose boards with nails. The boards contain nails that are protruding upward, are easily accessed by the animals, and can cause injury.

**There are missing and damaged tiles on the roofs of the outdoor shelters. This compromises the ability of the structure to provide adequate shelter and shade.

**Areas of wire fencing in the pasture are loose and have fallen down. This compromises the strength of the fencing and animals could become entangled in the wire.

**The ladder that leads to the hay storage on the top of the barn is missing a rung. This compromises the ability of both employees and APHIS officials to safely access the hay storage area.

To be corrected by: April 8, 2016

3.133 SEPARATION.

One of the goats (animal #28) is particularly combative with the other animals and was reported by staff to have caused numerous injuries in the other goats. Personnel described the goat as ramming the other animals and lifting them into the air. In addition, this goat has horns while others do not, allowing for more injuries. Animals shall not be housed with other animals if they are not compatible, as they can cause injury, interfere with feeding or cause them discomfort. Any animals that are not compatible must

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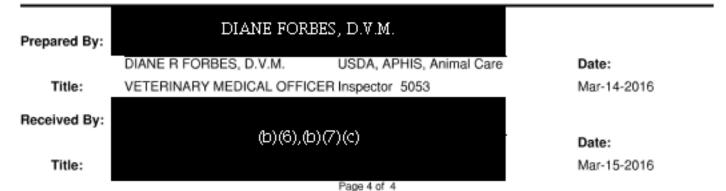
Inspection Report Explanation: http://www.aphis.usda.gov/animal_welfare/downloads/IR_Explanation.pdf

not be housed in the same enclosure.

To be corrected by: March 18, 2016

Note: This is the inspection report for all non-compliances on March 3, 2016 that were not cited as direct noncompliances. In addition, a record review was not conducted at that time.

An exit interview was conducted with the facility representative, Dr. Carolyn McKinnie, SACS, and Dr. Diane Forbes, VMO.





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Customer ID: 331329 Certificate: 91-R-0072 Site: 001 Pi Bioscientific Inc.

Type: ROUTINE INSPECTION

Date: Mar-03-2016

2.33 (b) (2)

DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Over half of the goat herd (24 out of 42 animals) was afflicted with various ailments and severe medical problems to include emaciation, diarrhea, lameness, overgrown hooves, coughing and upper respiratory disease. Low body weight and emaciation can indicate a parasite problem, dental issues or overall poor health. Diarrhea can also indicate a parasite problem or other diseases. Overgrown hooves can lead to lameness and make movement difficult and extremely painful. It can stress ligaments and joints from the abnormal movement. Coughing may indicate respiratory disease, parasites or other diseases.

*** Goat #45, a female Nubian, is emaciated with a body score of 1 out of 5 with protruding hip bones and spinal processes. The animal was coughing and had mucoid discharge around the nostrils and eyes. In addition, she was observed holding the left rear leg up and walking stiffly in the rear legs. All hooves were overgrown.

*** Goat #19, a female Nubian, is emaciated with jutting hip bones and spinal processes and a body score of 1 out of 5. The animal also has diarrhea with dried feces in the tail area and down the rear legs.

*** Goat #15, a female Boer, was observed lying down, depressed and reluctant to move. Once she began to walk, she held up the left foreleg and limped as she moved forward painfully. The animal also has diarrhea and the hooves are overgrown.

*** Goat #35, a female Boer, is lame with severely overgrown hooves, especially in the right foreleg where the hoof is widened and flattened like a plate. The hoof on the left foreleg is overgrown and the goat was observed chewing on the foot.

*** Goat #14, a female Boer, has severely overgrown hooves especially in the rear feet. The hooves are curved and twisted and approximately 5 inches in length.

*** Goat #40, a female Saanen, is severely lame. The animal is holding the left rear leg up and struggling to move as it limps forward. She has diarrhea with dried, caked feces around tail area.

*** Goat #29, a white Angora mix, is severely lame with non-weight bearing lameness in right rear leg.

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r topatoù byt	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:
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The animal is holding the leg up at rest and limping as it walks forward.

*** Goat #32, a Boer wether, has severe diarrhea with feces covering the tail, hind end and rear legs. The animal is extremely emaciated with a body score of 0 out of 5. In addition, he has overgrown hooves on all four legs.

*** Goat #23, a Toggenburg mix female, was emaciated with a body score of 2 out of 5. The animal had diarrhea with greenish liquid stool present under and around the tail and the hooves were overgrown.

All of the goats above (#45, #35, #15, #19, #14, #40, #29, #32, #23) must be seen, diagnosed and treated by the attending veterinarian no later than March 4th, 2016 at 1:00 pm. All veterinary documentation must be made available to APHIS personnel upon request.

Goat #28, a female Alpine mix, has overgrown hooves.

Goat #41, a female LaMancha, has overgrown hooves.

Goat #8, a wether, has diarrhea with dried, caked feces on rear legs.

Goat #9, a female Boer, has diarrhea with dried, caked feces on rear legs.

Goat #5, a female Boer, has overgrown hooves on all four feet.

Goat #34, a female Boer, has severely overgrown hooves that are broken and twisted.

Goat #22, a female Boer, has severely overgrown hooves, especially in the right front leg. This animal high steps while walking as hooves appear to get in the way of normal movement.

Goat #44, an Alpine female, has overgrown front hooves.

Goat #2 has diarrhea with dried fecal material present and the anal area appears swollen from irritation.

Goat #47 has diarrhea with fecal debris dried around tail area.

Goat #30, an Alpine female, is coughing.

Goat #4, a Boer female, is coughing.

Goat #33, a female Boer mix, has diarrhea and overgrown hooves.

Goat #21, a white mixed breed, has overgrown hooves on all four feet.

All of the following goats (28, 41, 8, 9, 5, 34, 22, 44, 2, 47, 30, 4, 33, 21) must be seen, diagnosed and treated by the attending veterinarian no later than March 7th, 2016 at close of business. All veterinary documentation must be made available to APHIS personnel upon request.

2.33 (b) (3)

DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Over half of the goat herd (24 out of 42 animals) was afflicted with various ailments and severe medical problems. These medical issues were not reported to the attending veterinarian. Prompt reporting and discussion of animal health issues with the attending veterinarian is essential and must occur to prevent diseases and other medical issues from worsening, thus leading to undue suffering by the animals. A mechanism of direct and frequent communication must be established and maintained so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending

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veterinarian. To be corrected immediately.

3.131 (a)

DIRECT NCI

SANITATION.

The barn for the animals was full of fecal material and wet throughout, so that none of the animals had a clean or dry area they could access. Lack of a clean, dry facility will lead to severe discomfort and disease in the animals. Areas included the sleeping and feeding areas, and also the walkways for the animals. To be corrected by close of business on March 7, 2016.

Note: This inspection report includes only the direct non-compliances. A subsequent report will be prepared to document all other non-compliances noted at the time of inspection.

An exit interview was conducted on March 4, 2016 with the facility representative, Dr. Carolyn McKinnie, SACS, and Dr. Diane Forbes, VMO.

Prepared By: DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care Date: Title: VETERINARY MEDICAL OFFICER Inspector 5053 Mar-07-2016	
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Received By: (b)(6),(b)(7)(c) Date:	
Title: Mar-04-2016	



Pi Bioscientific Inc. 8315 Lake City Way N E Seattle, WA 98118

Customer ID: 331329 Certificate: 91-R-0072 Site: 001 Pi Bioscientific Inc.

Type: ROUTINE INSPECTION Date: Mar-08-2016

2.31 (b) (3) (ii) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The public member on the IACUC is affiliated with the research facility. The unaffiliated member is intended to provide representation for the general community interests in the proper care and treatment of animals. The facility must ensure that at least one member of the IACUC is not affiliated with the facility in any way other than being a member of the Committee.

To be corrected by: April 15, 2016

2.31 (c) (1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC is not conducting a program review at least once every six months. A review was conducted in 2014, and the next review did not occur until November 5, 2015. The IACUC must review the research facility's program for humane care and use of animals to ensure that animals are utilized in a manner that minimizes pain and distress. The IACUC must review the research facility's program for humane care and use of animals at least once every six months.

Correct from this time forward for all program reviews.

2.31 (c) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC is not conducting inspections of the research facility's animal facilities at least once every six months. IACUC records indicate an inspection occurred in 2014; however, the IACUC was not scheduled to conduct the next inspection until December 2, 2015. In addition, there is no documentation that this inspection actually took place. Inspection of the animal areas must be conducted to ensure that animals used in research activities are maintained under humane conditions and meet all of the regulatory requirements of the Animal Welfare Act.

The IACUC must inspect, at least every six months, all of the research facility's animal facilities including

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, ,	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:	
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the animal study areas.

Correct from this time forward for all facility inspections.

2.31 (c) (3) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

There is no documentation that a report of the facility inspection (scheduled for December 2, 2015) was prepared or that it was submitted to the Institutional Official of the research facility. In addition, the report for the program review conducted on November 5, 2015 was not reviewed and signed by the majority of the IACUC members.

The IACUC must prepare reports of its evaluations and submit the reports to the Institutional Official. In addition, reports for the program review and the facility inspection must be reviewed and signed by the majority of the IACUC members. The research facility must ensure that reports are generated for IACUC activities and made available to APHIS officials during unannounced inspections to ensure facility compliance with the Animal Welfare Act may be evaluated.

Correct from this time forward for all reports of facility inspections and program reviews.

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The protocol for the sheep and goats does not address the principal investigator's consideration of alternatives to the potentially painful and/or distressful procedures nor does it provide a written narrative of the methods to determine alternatives were not available.

It is the responsibility of the IACUC to review the protocol(s) to ensure the principal investigator has given consideration to alternatives to the potentially painful and/or distressful procedures and provided a written narrative describing the methods utilized to determine alternatives were not available.

To be corrected by: April 15, 2016

2.31 (d) (1) (iii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The principal investigator has not provided written assurance that the activities do not unnecessarily duplicate previous experiments. This statement ensures that the principal investigator has considered procedures that could prevent unintended and unnecessary duplication of research involving animals. This statement must be included in the description of proposed activities.

To be corrected by: April 15, 2016

Prepared By:	DIANE FORBES, D.V.M.	
	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:
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2.32 (b) PERSONNEL QUALIFICATIONS.

There are no training records documenting instruction or capabilities of any of the staff members of the research facility, and in particular for the animal care staff. In addition, the animal care staff has not been trained on methods to assure the health status of the animals as outlined in the protocol(s). The facility's Animal Care Protocol states:

**regularly (at approximately 3 week intervals), animals will be monitored for anemia by examination of the ocular mucosa and scored on a three point scale. However, the animal care staff has not been trained on how to perform this procedure.

**animals that score low (1= poor status) will be tested for their hematocrit status. The animal care staff has not been trained on how to conduct this procedure; further, there is no equipment in the lab to do so.

The protocol also states that "the maximum volume of blood expressed in milliliters that can be drawn from an animal will be no more than ten times its body weight expressed in kilograms". Personnel are possibly taking too much blood as an employee ordered 600 ml reservoir blood collection bags, when staff should have been using 300 ml bags. The staff has also not been trained to conduct body condition scoring.

It is the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. Training and instruction must be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facilities responsibilities.

To be corrected by: April 15, 2016

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The research facility had written Programs of Veterinary Care from two veterinarians. The APHIS Form 7002 from the attending veterinarian is filled out on page 1 only; the rest of the form is blank. There is no indication of the species involved, vaccinations, parasite control program, emergency care or description of euthanasia for the animals. This written Program of Veterinary Care must be completed in full, and include any medications/methods used, the route of administration, and the dose of the product.

To be corrected by: April 15, 2016

Prepared By:	DIANE FORBES, D.V.M.	
,,.	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:
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2.35 (f)

RECORDKEEPING REQUIREMENTS.

The research facility is not maintaining all records that relate directly to the proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC. These records apply directly to the proposals and include:

-weights of the sheep and goats
 -blood volumes on sheep/goats with the date, animal ID number, and the amount of blood obtained
 -hematocrit status of all animals at least once per year
 -scoring results based on examination of the ocular mucosa to assess anemia
 -crude hematocrit determination for animals that score low (1) when assessed for anemia

These records must be maintained for the duration of the activity and for an additional three years after completion of the activity. All records must be available for inspection and copying by APHIS officials.

To be corrected by: immediately

An exit interview was conducted with the facility representative, Dr. Carolyn McKinnie, SACS, and Dr. Diane Forbes, VMO.

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,,	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:
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Pi Bioscientific Inc. 8315 Lake City Way N E Seattle, WA 98118

Customer ID: 331329 Certificate: 91-R-0072 Site: 001 Pi Bioscientific Inc.

Type: ROUTINE INSPECTION Date: Mar-08-2016

3.131 (a) SANITATION.

REPEAT

The sheep/goat barn has been divided into five areas by the research facility. The following areas have been cleaned and provided with fresh bedding: #1(ill animal area), #4 (sleeping area) and #5 (feeding area). However, two remaining areas of the barn have not been cleaned. These are areas #2 and #3; with area #3 being used for feeding sheep and goats the pelleted ration. These areas still need the remaining manure removed and the floors washed.

This was a focused inspection for the direct non-compliances documented on March 3, 2016. The following animals were examined, diagnosed and treated by the attending veterinarian on March 4, 2016: Animal ID #: 45, 35, 15, 19, 14, 40, 29, 32, and 23.

In addition, the following animals were examined, diagnosed and treated by the attending veterinarian on March 7, 2016: Animal ID #: 28, 41, 8, 9, 5, 34, 22, 44, 2, 47, 30, 4, 33, and 21.

An exit interview was conducted with the facility representative, Dr. Carolyn McKinnie, SACS and Dr. Diane Forbes, VMO.

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	DIANE R FORBES, D.V.M. USDA, APHIS, Animal Care	Date:
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8315 Lake City Way N E	Certificate:	91-R-0072
Seattle, WA 98118	Site:	001
	Pi Biosci	ientific Inc.
	Type: Date:	ROUTINE INSPECTION 01-MAR-2018

2.33(b)(3) DIRECT REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Goat #20, a female Saanen, was thin with swollen carpal joints on both forelegs, and appeared to have difficulty walking. Low body weight and swollen joints can indicate a serious disease issue. Goat #3, a Boer mix, had overgrown hooves and was lame, as the animal was observed not putting full weight on the right hindleg when standing. These animals must be examined by a veterinarian by close of business on March 2, 2018. All veterinary documentation must be made available to APHIS personnel upon request.

Several of the goats and two sheep have overgrown hooves that will require trimming. These animals include sheep #48 and #12, and goats #33, #25, #26, and #34. Overgrown hooves can lead to lameness and make movement difficult. It can also stress ligaments and joints from the abnormal movement.

3.125(a) REPEAT

FACILITIES, GENERAL.

Peeling paint is present on the north side of the barn above the entrance for the animals. Peeling paint from the building can fall into the animal area and be ingested. The peeling paint must be repaired.

3.125(c)

FACILITIES, GENERAL.

Bags of pelleted feed are stored against the side of the room. An open bag of feed is present on the pallets, and spilled feed is present on the floor under the pallets. All supplies of food must be stored off the floor and away from the walls. Any open supplies of food must be stored in a sealed container with a lid. Spilled feed contributes to pest

Prepared By:	FORBES DIANE, D V M FORBES DIANE, D V M USDA, APHIS, Animal Care	Date: 05-MAR-2018
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Received By:		
Title:		Date: 05-MAR-2018



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Inspection Report

control issues. Food for the animals must be properly stored, and any spillage removed on a routine basis.

Correct by March 8, 2018.

3.131(c)

SANITATION.

A syringe with a capped needle was observed in the feeder for the animals. A power cord was present along the floor of the animal area in the barn. Buckets with various items were found sitting above the animal area in the barn, and could fall into the enclosure.

The animals could come in contact with these materials and injure themselves. The syringe/needle was removed at the time of inspection. All other items must be removed.

Correct by March 2, 2018.

This inspection and exit briefing were conducted with the facility representative.

Additional Inspectors Hallberg Gwynn, Veterinary Medical Officer

Prepared By:	FORBES DIANE, D V M FORBES DIANE, D V M USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFICER 5053	05-MAR-2018
Received By:		
Title:		Date: 05-MAR-2018



Pi Bioscientific Inc.	Customer ID:	331329
8315 Lake City Way N E	Certificate:	91-R-0072
Seattle, WA 98118	Site:	001
	Pi Biosc	entific Inc.
	Туре:	ROUTINE INSPECTION
	Date:	06-APR-2017

3.125(a)

REPEAT

FACILITIES, GENERAL.

The facility has repaired and upgraded most of the fencing for the animals since the last inspection. In addition, electric fencing has been added near the barn. However, several deficiencies were noted.

Sections of the wire fence had been bent outward in the center by the animals, thereby causing a small gap to be formed between the bottom of the fence and the ground. Several sections of the fence had broken or spliced areas with protruding wires.

In addition, protruding nails were seen where a wooden board in the barn has fallen as well as on a ramp on the collection chute. A solid sheet metal panel in a currently-unoccupied enclosure had been raised slightly at the bottom, resulting in an exposed sharp end.

The damaged areas compromise the strength of the fencing and animals could become injured by any sharp edges, protruding wires or loose nails. Additionally, an animal might escape through the gap under the fence or become entrapped or injured during such an attempt.

The facility promptly began repairing these issues during the inspection.

A system of routine monitoring and preventative maintenance of buildings, fences and equipment must be established by the facility.

Correct from this point forward.

This inspection and exit interview were conducted with the facility representatives.

Prepared By:	FORBES DIANE, D V M	
	FORBES DIANE, D V M USDA, APHIS, Animal Care	Date: 07-APR-2017
Title:	VETERINARY MEDICAL OFFICER 5053	
Received By:		
		Deter
Title:		Date: 07-APR-2017

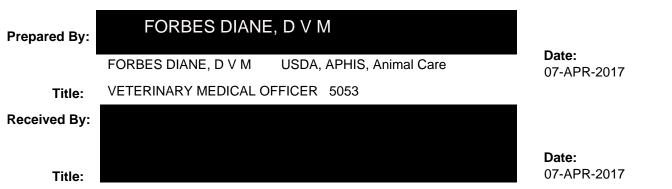


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Inspection Report

Additional Inspectors

Schnell Michael, Veterinary Medical Officer





Pi Bioscientific Inc. 8315 Lake City Way N E Seattle, WA 98118

Customer ID: 331329 Certificate: 91-R-0072 Site: 001 Pi Bioscientific Inc.

Type: ROUTINE INSPECTION Date: Nov-20-2014

2.31 (e) (1) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC (Institutional Care and Use Committee) approved protocol utilizing a regulated species did not identify the approximate number of animals to be used in the study.

The IACUC should ensure that a proposal to conduct activities involving animals includes the appropriate information prior to approving the proposal. Additionally, any significant changes to activities should have IACUC approval prior to their implementation.

Previous correction date: Correct by: No further animal activities should take place until the IACUC approves that activity.

2.33 (a) (1) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The written program of veterinary care was not available for review at the time of the inspection.

A written program of veterinary care is needed to ensure that the facility staff understands the expectations of the attending veterinarian in regards to the veterinary care of regulated animals. The facility should ensure that a written program of veterinary care is completed by the attending veterinarian and is available for review during APHIS inspections.

Previous correction date: Correct by September 24, 2014.

An exit briefing was conducted with a facility representative.

Prepared By:	MARCY ROSENDALE, D.V.M.	
	MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFICER Inspector 5039	Nov-25-2014
Received By:	(b)(6),(b)(7)(c)	Date:
Title:		Nov-25-2014
	Page 1 of 1	



Pi Bioscientific Inc. 8315 Lake City Way N E Seattle, WA 98118

Customer ID: 331329 Certificate: 91-R-0072 Site: 001 Pi Bioscientific Inc.

> Type: ROUTINE INSPECTION Date: Sep-10-2014

2.31 (b) (3) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The facility Institutional Care and Use Committee (IACUC) did not have an unaffiliated member. The unaffiliated member is intended to provide representation for the general community interests in the proper care and treatment of animals. The facility should ensure that at least one member of the IACUC is not affiliated with the facility in any way other than being a member of the committee.

Correct by October 17, 2014.

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

No reports of any evaluations conducted to review the facility's program for humane care and use of the animals or inspect the animal facilities were available for review at the time of the inspection. The facility should ensure that reports are generated for IACUC activities and made available to APHIS officials during unannounced inspections in order that facility compliance with the Animal Welfare Act may be evaluated.

Correct by October 17, 2014.

2.31 (e)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The facility did not have a written protocol that contained required information pertaining to animal use. The required information should have included; the rationale for the species and number of animals to be used, a complete description of the proposed use of the animals, a description of procedures designed to

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	MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care	Date:
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Received By:	(b)(6),(b)(7)(c)	Date:
Title:	Page 1 of 3	Sep-17-2014



assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, and a description of any euthanasia method to be used.

The IACUC should ensure that a proposal to conduct activities involving animals includes the appropriate information prior to approving the proposal. Additionally, any significant changes to activities should have IACUC approval prior to their implementation.

Correct by: No further animal activities should take place until the IACUC approves that activity.

2.33 (a) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The facility had no written program of veterinary care. A part-time veterinarian is employed and had visited the facility to care for sick animals but had not provided a written program of veterinary care.

A written program of veterinary care is needed to ensure that the facility staff understands the expectations of the attending veterinarian in regards to the veterinary care of regulated animals. The facility should ensure that a written program of veterinary care is completed by the attending veterinarian and is available for review during APHIS inspections.

Correct by September 24, 2014.

3.125 (a)

FACILITIES, GENERAL.

A strand of barbed wire fencing placed along the top of a section of wire fence had broken. Inside the barn bare wires and uncovered electrical outlets were present at a level that could be accessed by the animals. A gate with a large gap was being held together with baling twine at the bottom so that animals could not escape.

Animal housing should be structurally sound and maintained in good repair to protect the animals from harm and contain them. Exposed electrical wires and uncovered outlets pose a fire risk and could also cause injury to animals if chewed. Barbed wire may cause injuries and should be replaced with more suitable fencing.

Correct by September 24, 2014.

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Title:	VETERINARY MEDICAL OFFICER Inspector 5039	Sep-17-2014
Received By:	(b)(6),(b)(7)(c)	Date:
Title:	Page 2 of 3	Sep-17-2014



3.129 (a)

FEEDING.

A gasoline powered leaf blower was being stored on the floor next to the hay. A bag and a block of unknown substances were found on top of a stack of hay. Machinery can leak gasoline or oil that could contaminate food and should not be stored in close proximity to animal food. Items that could contaminate animal food should not be placed on or above food or food containers. Partially used bags or containers of food or supplements should be kept closed or covered to keep vermin and dirt from contaminating the contents.

Contaminated food may adversely affect animal health. Food should be stored in such a manner that it remains wholesome, palatable, and free from contamination.

Correct by September 19, 2014.

3.131 (c)

SANITATION.

A pasture and barn housing 65 animals contained debris that could cause injury to the animals. A nail and strand of barbed wire were protruding from what appeared to be a portion of an old wooden fence on the ground in the pasture. A golf ball and a long piece of plastic pipe were also noted in the pasture. Pieces of boards with protruding nails and a broken shovel were found on the ground in an aisle connecting the pasture with the barn. Shelves containing tools, a glass bottle, and a gasoline container were present in the barn at a level that could be accessed by the animals. A fire extinguisher was mounted on a wall at a level that could be accessed by the animals. Several fence panels and wheelbarrows were being stored against a wall inside the barn. The fence panels could be knocked over on animals and hooves or legs could be become caught in the wheelbarrows or fence panels.

Debris and inappropriate objects in animal housing areas could harm the animals. Animal housing should be inspected on a regular basis and any trash or debris should be promptly removed. Equipment and supplies should be stored in an area that is not accessed by the animals.

Correct by September 24, 2014.

An exit briefing was conducted with a facility representative.

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Received By:	(b)(6),(b)(7)(c)	Date:
Title:		Sep-17-2014
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EXHIBIT 4



Robert Sargeant 655 Ash Street Ramona, CA 92065

Customer ID: 1115 Certificate: 93-R-0283 Site: 001 ROBERT SARGENT

> Type: ROUTINE INSPECTION Date: Mar-17-2016

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving rabbits and goats did not contain an adequate rationale for the appropriateness of the species or the numbers of these animals to be used. The protocol stated that two rabbits and one goat are normally adequate but that in cases of larger needs then more animals may be required; however there is no quantity or range provided which corresponds to how many more numbers of the animals this would require. There is not an explanation given to justify the numbers of animals currently being used to make the procedures valid.

The rationale approved by the IACUC should provide assurances for the appropriateness of the species and that the appropriate number of animals is being used to obtain the information the activity is designed to provide.

It is the responsibility of the IACUC to ensure that proposals to conduct activities involving animals contain rationales that explain the appropriateness of the species and the number of animals to be used in those activities.

To be corrected for all future inspections.

2.31 (e) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving rabbits and goats did not provide a complete description of the method of euthanasia used. The protocol stated euthanasia would be by intravenous pentobarbital sodium. There is no documentation of the dosage used for the covered animals (rabbits/goats) or a description of the procedure which is followed for euthanizing animals. The IACUC should review proposed activities involving animals to ensure there is a complete description of the method of euthanasia to be utilized that is in accordance with established standard veterinary practices and regulatory requirements of the act.

Prepared By:	TYLER FIELDS, V.M.O.	
	TYLER W FIELDS, V.M.O. USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFICER Inspector 6082	Mar-25-2016
Received By:	(b)(6),(b)(7)(c)	Date:
Title:		Mar-25-2016
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To be corrected for all future inspections.

3.51 (d)

FACILITIES, INDOOR.

In the rabbit barn, the majority of rabbit enclosures are moderately covered in rust. There was a section of new cages and feeders which had replaced older ones. The presence of rust may prevent the required cleaning and sanitizing of the enclosures, which may adversely affect the health and well-being of the animals. The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

Correct by 12/31/2016

3.56 (c)

SANITATION.

-Several empty rabbit enclosures had not been cleaned since last occupied by the animals. A large section of enclosures were heavily covered with dust and cobwebs while others were soiled and contained what appeared to be dried fecal matter and other mixed food/waste material. These enclosures were located in the same area and directly adjacent to other rabbits. According to the facility representative, the cages are not cleaned until rabbits are placed in them.

Several overhead and ceiling areas of the barn had a moderate buildup of cobwebs with some being located directly
over rabbit cages.

-There was a heavy buildup of fecal matter and other waste material along the walkways between rows of cages, underneath several of the rabbit cages, and in areas on the ground near the base of large building support beams.

Decomposing organic/waste material may create noxious odors, attract vermin, and potentially create disease hazards thus adversely impacting the health and well-being of the animals housed nearby. Premises (buildings and grounds) shall be kept clean in order to facilitate the prescribed husbandry practices set forth in this subpart.

A system should be in place to ensure areas surrounding animal housing areas are cleaned as required to protect the health and well-being of the animals.

Correct by 06/30/2016

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Received By:	(b)(6),(b)(7)(c)	Date:
Title:		Mar-25-2016
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3.56 (d)

SANITATION.

Several flies were observed in the rabbit barn at time of inspection. No functional flytraps or other fly control products/methods are presently being used. Control of insects and other pests is needed to reduce contamination and potential disease hazards and to promote the health and well-being of the animals. An effective program of pest control must be established and maintained.

Correct by 04/04/2016

Exit interview conducted with facility representative, Dr. Alexandra Andricos, VMO and Dr. Tyler Fields, VMO.

