



Animal and Plant
Health Inspection
Service

Animal Care
Western Region

2150 Centre Avenue
Building B, 3W11
Fort Collins, CO
80526
Phone: 970/494-7478
Fax: 970/494-7461

ATTN: Name
Facility Legal Name
Address
City, State, Zip

Dear Registrant:

RE: ANNUAL REPORT
Certificate Number:

Fiscal Year: 2015
August 24, 2015

Customer ID Number:

Animal Welfare Act regulations require all research registrants to file an *Annual Report of Research Facility* (APHIS Form 7023 and 7023A) with the Animal Care Regional Office documenting their activities and animal usage for that particular fiscal year (October 1 through September 30). These reports are due by December 1 of each year. Even if you did not use or hold any animals during the fiscal year, you still need to complete and submit an *Annual Report*. Likewise, registrants whose registrations were canceled or terminated during the fiscal year must complete and submit an *Annual Report*. Failure to do so constitutes a violation of the Animal Welfare Act regulations.

All *Annual Reports* must be mailed to the Regional Offices with an original signed signature. You may either 1) fill out the enclosed forms or 2) print fillable 7023 and 7023A forms via this link:
http://www.aphis.usda.gov/animal_welfare/annual_report_forms.shtml.

Please fill out all applicable fields, including the signature of the Chief Executive Officer or the legally responsible institutional official. Also, please make sure that you have properly verified each total in Column F.

After you complete the form(s), please make a copy for your records and then mail the original(s) to the address listed on the left side of this page. Detailed instructions are provided in the enclosed *Annual Report Checklist*.

Thank you for your prompt attention to this matter. We appreciate your efforts in adhering to the Animal Welfare Act regulations.

If you have any questions, please contact us at (970) 494-7478.

Sincerely,

Robert M. Gibbens, D.V.M.
Regional Director – Animal Care
Western Region

cc: , D.V.M.

Enclosures

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year: 2015

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

REGISTRATION NUMBER

Customer Number:

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include ZIP Code)

Facility Legal Name

Address

City, State, Zip

Telephone

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A.	B.	C.	D.	E.	F.
Animals Covered By The Animal Welfare Regulations	Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED

APHIS Form 7023 Site Addendum for FY: 2015

Registration Number: _____
Customer ID Number: _____

Facility Business Address Information:

Facility Legal Name

Address

City, State, Zip

Telephone

Facilities Site(s) Address Information:

Site Code(s):

001

Assigned Inspector:  D.V.M.

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
 - 2.) Each principal investigator has considered alternatives to painful procedures.
 - 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
 - 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)	DATE SIGNED
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INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023

(Refer to 9 CFR Part 2, Subpart C, Sections 2.33 and 2.36)

ITEM 1 - Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).

ITEM 2 - Enter the complete name and address of the Headquarters Research Facility as registered with USDA.

ITEM 3 - List location of each Facility or Site where animals were housed and used in actual research, testing, teaching, or experimentation, or held for these purposes. *(Attach additional sheets if necessary.)*

ITEM 4 - 13 - DO NOT enter numbers in Column A. DO NOT add numbers entered in Column B into the total in Column F. Column F is to show total numbers entered in Columns C + D + E. Entries in Column E must be explained on attached sheet(s).

ITEM 12 - List by common name all other farm animal species.

ITEM 13 - Other: List, by common name, all other warm-blooded animal species covered by the Regulations. *(This will include all wild or exotic species.)* Attach additional sheets if necessary or use APHIS Form 7023A.

CERTIFICATION: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to legally commit on behalf of the Registered Research Facility. Sign, print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE REGIONAL OFFICE.

Annual Report Reminders

September 2015

Only one Annual Report should be submitted per registered research facility. Consolidate site numbers onto one report for submission. Site specific numbers should be available to the inspector at each site.

Animals used for research purposes at any time during the reporting year must be reported in Column C, D or E, as appropriate, whether or not they are still being held at the facility.

All animals contained on the facility's inventory on September 30, that were not used in a research project, should be reported in column B. Animals that were held but died during the year without being used for research purposes should also be reported in column B. Animals held, but not used in research during the reporting year, that have been moved to another facility and are not present at the facility on September 30 should only be reported by the facility in possession of the animals.

Facilities with breeding colonies should report their breeding animals and any offspring which are not being used for research purposes in Column B.

Animals present at the facility which were used for research in previous years but were not used in the current year would also be reported in Column B.

Animals used in more than one protocol are counted once in the most painful/distressful category.

Report wild rodents. Do not report the use of laboratory rats, laboratory mice, birds, reptiles, fish, or other animals which are exempt from regulation under the AWA.

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: _____
2. Number _____ of animals used in this study.
3. Species (common name) _____ of animals used in the study.
4. Explain the procedure producing pain and/or distress.
5. Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used. (For Federally mandated testing, see Item 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____



Assistance with Accurate Annual Reporting for Research Facilities

September 2015

In order to assist research facilities in accurately reporting animal use on the Annual Report, APHIS Form 7023, Animal Care is providing the following information and examples as guidance only. Research activities are often unique and specific questions not covered by these examples should be directed to the appropriate Regional Office.

Animal Care and Use Review

When an Animal Care and Use Proposal is reviewed, the IACUC must make a determination as to whether the procedure could potentially cause more than slight or momentary pain or distress. If the IACUC determines that the procedures could potentially cause more than slight or momentary pain or distress, the investigator must consider alternatives to all the procedures in that study that may cause pain or distress.

At that time, the IACUC must also review the scientific explanation for justifying the withholding of analgesics, anesthetics or tranquilizing drugs that could be used to relieve the pain or distress animals on the study might experience. If the animals do experience pain which cannot be relieved with appropriate anesthetics, analgesics or tranquilizing drugs, because they would adversely affect the study, those animals are reported in column E with the explanation and reason why pain and distress could not be relieved.”

Annual Report of the Research Facility

Occasionally, during the course of a research project unforeseen events involving animals occur, and questions arise as to how best to report these animals on the APHIS Form 7023. Unexpected pain or distress and animal incidents unrelated to ongoing research should be brought to the attention of the IACUC for purposes of adequate protocol and program review.

The following examples are not intended to address protocol review, veterinary care, or training and qualification requirements. Animal Care is providing the following examples as guidance for annual reporting purposes only.

Example 1) An animal experiences unexpected pain due to the research procedures, during the course of a study. The pain is recognized and treated with appropriate analgesics in a timely manner.

Answer: Reported in Column D.



Example 2) An animal experiences unexpected pain due to a research procedure but when the pain is recognized, the investigator determines that analgesics, anesthetics or tranquilizers would adversely affect the study.

Answer: Reported in Column E.

Example 3) An animal is unexpectedly found dead in the cage during the course of a study. The animal had been monitored appropriately and there were no pre or post mortem sign of pain or distress. The animal had not experienced pain as part of the study prior to its death.

Answer: Reported in Column C.

Example 4) An animal experiences unexpected pain or distress due to the research procedures during the course of a study. The pain is recognized and the animal is euthanized in a timely manner.

Answer: Reported in Column D.

Example 5) An animal accidentally becomes caught in a cage and experiences pain and distress which is completely unrelated to the study. The injuries are treated and appropriate analgesia is provided.

Answer: This animal should be reported in the pain category appropriate to its experiences in the study. The accident does not affect the reporting category. If the animal did not experience any pain or distress as part of the approved study it would be reported in Column C.

Example 6) An animal develops an ear infection and experiences pain or distress entirely unrelated to the study. Analgesics, anesthetics or tranquilizers would adversely affect the study so the animal is treated with palliative husbandry methods.

Answer: This is a tough one and does not fit easily into any of the classifications. Because the pain relief must be withheld due to the study, even though the pain is not caused by a research procedure, report this animal in Column E and provide a justification for not providing pain relieving analgesics.

Exception/Exemption

The following are guidelines for determining when an Exception/Exemption should or should not be reported on the Annual Report. This information is excerpted from the Animal Care Inspection Guide, Chapter 7, Pages 7-26 – 7-27, February 2015 edition.

Exceptions/Exemptions

Exceptions or exemptions to a particular AWA Regulation or Standard **approved by the IACUC** must be:

- ◆ For scientific reasons
- ◆ Justified in writing

If a regulation or standard also provides specific parameters for an exemption/exception, those parameters must be followed.

Exceptions that **should** be reported on the Annual Report:

- ◆ Exceptions approved by the IACUC under 2.38(k) that are **not** provided for under the Regulations and Standards, including but not limited to:
 - ❖ Removal of resting platforms from cat enclosures
 - ❖ Extension of interval for cleaning/sanitization of enclosures
 - ❖ Keeping animals in 24 hour dark cycle
 - ❖ Keeping animals in temperatures outside range described in Part 3—Standards for species
- ◆ Exceptions approved by Animal Care, including but not limited to:
 - ❖ Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on **more than one protocol** (2.31)(d)(1)
 - ❖ Exception to the health certificate requirements ((2.38)(h))
 - ❖ Temporary tethering of dogs used as the primary enclosure (3.6)(c)(4)

Exceptions that should **not** be reported on the Annual Report:

- ◆ Exceptions approved by the IACUC that are provided for under the Regulations and Standards, including but not limited to:
 - ❖ Approval for use of an animal in more than one major operative procedure from which it is allowed to recover on **one protocol** (2.31)(d)(1)
 - ❖ Short term withholding of food and water from animals (2.38)(f)(2)
 - ❖ Exemption of an individual NHP from some or all of the environmental enhancement plan (3.81)(e)(2)
 - ❖ Any deviation from the methods of euthanasia as defined in the AWA regulations which were justified for scientific reasons, in writing, by the investigator (2.31)(d)(1)(xi)
- ◆ Exceptions approved by a veterinarian as part of the provision of veterinary care, including but not limited to:
 - ❖ Animal is fasted for surgery conducted for husbandry reasons
 - ❖ Animal is housed in an enclosure that does not meet space requirements for medical reasons while recovering from husbandry or veterinary care related surgery
 - ❖ Animal develops vomiting/diarrhea (not study related) and veterinarian prescribes IV fluids and severely restricts food and water intake by mouth for several days

Subject:	Expired Medical Materials Pharmaceutical-Grade Substances Surgery Pre- and Post- Procedural Care Program of Veterinary Care Declawing in Wild/Exotic Carnivores and Removal/Reduction of Canine Teeth in Wild /Exotic Carnivores and Nonhuman Primates Health Records Euthanasia
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References:	AWA Section 2143 9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40 9 CFR, Part 3, Section 3.110
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History:	Replaces memoranda dated May 31, 1990; November 29, 1991; April 6, 1992; and September 25, 1992. Replaces policies dated April 14, 1997; January 14, 2000; August 18, 2006; July 17, 2007; and March 25, 2011.
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Justification:	Provides requested guidance. The Animal Welfare Act (AWA) requires that all regulated animals be provided adequate veterinary care.
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Policy:	Expired Medical Materials
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The use of expired medical materials (e.g., drugs, fluids, sutures, anesthetics, sedatives, or analgesics) during any survival surgical procedure on a regulated species is not considered acceptable veterinary practice and therefore not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.

Research, Teaching, and Testing

Acute Terminal Procedures: Expired medical materials except analgesics, sedatives anesthetics, and euthanasia solutions may be used in acute terminal procedures where an animal is anesthetized during the study and euthanized without recovery if such use does not adversely affect the animal's well-being or compromise the validity of the scientific study.

Facilities permitting the use of expired medical materials in acute terminal procedures should have a policy on the use, storage, and disposal of such materials which is in accordance with all relevant institutional, local, state, and federal requirements where applicable; and/or require

investigators to describe the intended use in the animal study proposal.

Pharmaceutical-Grade Substances

Pharmaceutical-grade substances are expected to be used whenever they are available, even in acute procedures. This includes but is not limited to: compounds, medications, drugs, vehicles, and diluents. APHIS recognizes that some substances (e.g. test articles, novel compounds, and those resulting from a compounding process) are only available as a non-pharmaceutical grade product.

Research, Teaching, and Testing:

Non-pharmaceutical-grade substances should only be used in regulated animals after specific review and approval by the IACUC. The IACUC should develop a consistent evaluation process which includes but is not limited to the scientific justification and the availability of an acceptable veterinary or human pharmaceutical-grade product.

Cost savings alone is not sufficient justification for using a non-pharmaceutical-grade substance in regulated species, however, unavailability or shortages of pharmaceutical grade substances may lead to cost increases and the IACUC may determine that this justifies the use of the non-pharmaceutical grade substitution.

Exhibitors and Dealers:

Non-pharmaceutical-grade substances should only be used in regulated animals under the approval of the attending veterinarian in accordance with accepted veterinary practice and nursing care.

Surgery

Surgery is to be performed using appropriate anesthesia in accordance with professionally accepted medical and veterinary practice. Current standards preclude food preparation, eating, drinking, or smoking in surgery areas.

Research, Teaching, and Testing:

Survival Surgery: Survival surgery is to be performed using aseptic technique under standards that are in accordance with professionally accepted medical and veterinary practice. The AWA regulations require major operative procedures on nonrodents to be performed in a dedicated surgical facility. For the purposes of this policy, a designated

surgical facility is one that is set up to be cleaned and maintained in an aseptic condition, and not used for other purposes when not in use. It must be maintained in good repair to meet aseptic requirements. Meeting rooms and auditoriums do not qualify as dedicated survival surgical facilities.

Nonsurvival Surgery: Nonsurvival surgery does not require aseptic techniques or dedicated facilities. It should be performed in a clean area, free of clutter, using acceptable veterinary sanitation practices equivalent to those used in a standard examination/treatment room. Personnel present in the area should observe reasonable cleanliness practices for both themselves and the animals.

Pre- and Post-Procedural Care

The attending veterinarian is to ensure there is adequate pre-procedural and post-procedural care in accordance with established veterinary and medical practices.

Research, Teaching, and Testing:

All animal activity proposals involving surgery must provide specific details of pre- through post-procedural care and relief of pain and distress. The principal investigator must involve the attending veterinarian or his/her designee in planning the type of care that may be provided. The appropriate use of drugs to relieve pain and/or distress should be specified in the animal activity proposal to avoid possible delays due to investigator concerns that a treatment regimen may interfere with the study. The withholding of pain and/or distress relieving measures must be scientifically justified in writing and approved by the IACUC. The specified drugs for relief of pain and/or distress must be readily available for use as described in the proposal.

The attending veterinarian retains the authority to alter post-operative care if unexpected pain and/or distress occur in an animal. In the event the attending veterinarian requests a significant change to a protocol to alter post-operative care for the remaining animals, that change must be reviewed and approved by the IACUC before the change is implemented.

In the event the animal is taken to an off-site location, such as a farm for post-operative care, that location should be identified as a site of the research facility or a site of another registered research facility in order for Animal Care (AC) to conduct an inspection. To comply with adequate veterinary care

requirements and in accordance with currently accepted standards of practice, an animal is not to be taken to an off-site location before it fully recovers from anesthesia unless justified in the animal activity proposal.

Appropriate post-operative records should be maintained in accordance with professionally accepted veterinary procedures.

Program of Veterinary Care

Research facilities, dealers, and exhibitors

Establishments which do not have a full-time attending veterinarian must have a written Program of Veterinary Care (PVC). This Program must consist of a properly completed APHIS Form 7002 or an equivalent format. The attending veterinarian must visit the facility on a regular basis, i.e., often enough to provide adequate oversight of the facility's care and use of animals. APHIS recommends this visit occur at least annually. Records of visits by the attending veterinarian should be kept to include dates of the visits and comments or recommendations of the attending veterinarian or other veterinarians.

The PVC should be reviewed and updated whenever necessary (e.g., as a new species of animal or a new attending veterinarian is obtained, or the preventive medical program changes). APHIS recommends that the PVC be initialed and dated by both the attending veterinarian and the facility representative whenever it is changed or reviewed without change. The preventive medical program described in the PVC is expected to be in accordance with professionally accepted veterinary practice (e.g., appropriate vaccinations, diagnostic testing). It should include zoonotic disease prevention measures.

Declawing in Wild /Exotic Carnivores and Removal/Reduction of Canine Teeth in Nonhuman Primates and Wild /Exotic Carnivores

Declawing of wild and exotic carnivores and the removal or reduction of canine teeth in nonhuman primates and wild and exotic carnivores have been used in the past as a means to minimize the dangers during human interaction with these species. These procedures are not innocuous and can cause ongoing pain, discomfort, or other pathological conditions in the animals. In addition, they do not safeguard the public or the animals from biting and predatory behaviors.

The declawing of any wild or exotic carnivore does not constitute

appropriate veterinary care unless prescribed by the attending veterinarian for treatment of individual medical problems of the paws. Any medical treatment should be limited to the affected digit(s) or area.

Tooth reduction that exposes the pulp cavity does not constitute appropriate veterinary care as it may result in oral pathologic conditions and pain. Reduction that does not expose the pulp cavity may be acceptable in some instances such as a behavioral study or a breeding situation.

The American Veterinary Medical Association (AVMA) has developed a policy statement on these issues that supports APHIS' recommendation. It also suggests alternatives to dental surgery such as behavioral modification, environmental enrichment, and changes in group composition. A full text of AVMA Animal Welfare Policy Statements can be found on www.avma.org.

Health Records

Health records are needed to convey necessary information to all people involved in an animal's care. Every facility should have a system of health records sufficiently comprehensive to demonstrate the delivery of adequate health care.

Traveling exhibitors: Information on any chronic or ongoing health problems and information on the most current preventive medical procedures should accompany any traveling animals, but the individual medical history records may be maintained at the home site.

Euthanasia

The method of euthanasia should be consistent with the current AVMA Guidelines for the Euthanasia of Animals:

<https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx>.

Also note that in accordance with the "Expired Medical Materials" section of this policy, the use of expired euthanasia drugs is considered inadequate veterinary care.



Animal and Plant
Health Inspection
Service

Marketing and
Regulatory
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Animal and
Plant Health
Inspection
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Legislative and
Public Affairs

Freedom of
Information

4700 River Road
Unit 50
Riverdale, MD
20737-1232

September 1, 2015

RE: Annual Report of Research Facility Column E and Exception Attachments (FY 2015)

Dear Registrant:

Because of the enormous amount of resources expended each FY to review the Annual Report of Research Facility Column E and Exception Attachments (Report Attachments), and because of the continued public interest in this information, APHIS is continuing to make proactive disclosures of this information. This letter serves as notice that the enclosed records are being considered for proactive public disclosure on our Animal Care (AC) website. Previous disclosures of this type of information can be accessed by directing your browser to <https://acissearch.aphis.usda.gov/LPASearch/faces/Warning.jspx>.

TRADE SECRETS AND CONFIDENTIAL BUSINESS INFORMATION

These types of records may contain trade secrets or confidential business information (CBI) that may qualify for withholding under Exemption 4, 5 U.S.C. 552(b)(4) of the FOIA. For purposes of this exemption, the Court of Appeals for the District of Columbia Circuit in Public Citizen Health Research Group v. FDA, defines a trade secret as a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." This definition also incorporates a requirement that there be a "direct relationship" between the trade secret and the productive process. Information that does not qualify as a trade secret falls within the second, much larger category, confidential business information (CBI). To be protected as such, the information must be commercial or financial, obtained from a person, and privileged or confidential.

NON-FEDERAL RESEARCH FACILITIES

APHIS wishes to take into account your organization's views on whether any of the information contained in the records you will be submitting to our Animal Care (AC) office should be considered CBI and therefore exempt from disclosure under the FOIA in accordance with Executive Order 12,600 and 7 C.F.R. 1.12. Both the Executive Order and the cited regulation require that whenever a USDA agency cannot readily determine whether responsive records contain CBI, that agency must obtain and consider the views of the organization that submitted the information. In addition, the agency must provide the organization with an opportunity to object to any final decision to disclose the information. Therefore, we ask that you please provide your organization's opinion on whether the records contain information that is:

- 1.) Commercial or financial,
- 2.) Obtained from a person, your (or another) company, organization, state government, or other outside entity.
- 3.) "Confidential" which typically means that release of the information would cause substantial competitive harm to the submitter. In order to establish substantial competitive harm, you must identify the competition in the relevant market.

FEDERAL/VA RESEARCH FACILITIES

APHIS is seeking your recommendations on which, if any, portions of the records you will be submitting to the Animal Care (AC) office should be redacted pursuant to the FOIA. It may be

helpful to contact your agency's Freedom of Information office, for assistance in processing this consultation as they are responsible for making the release determinations for your agency's records. Please include in your submissions any pertinent background information pertaining to the records, such as whether the information was developed in partnership with any non-government entities.

RESPONDING TO THIS NOTICE

Please review the enclosed instructions before preparing your response. You may find it helpful to consult the resources listed at the end of the document or legal counsel. Be advised that comments provided by your organization in response to this letter may be subject to disclosure under the FOIA.

NO OBJECTIONS RESPONSE AND FAILURE TO RESPOND

If you do not object to the release of the records, please return the last page of this letter by fax/email or send an email to glendora.gilchrist@aphis.usda.gov which states that you have reviewed the material and have no objection to its release pursuant to the FOIA. If you fail to respond to this notice, we will assume that you have no objections to disclosure of the information contained in the records, but will advise you in writing before a disclosure takes place and give you an opportunity to seek judicial intervention.

CBI JUSTIFICATION SUBMISSIONS

In your submission, please include with the final page of this letter a copy of the records in which you highlight, underline, or otherwise clearly mark all information you believe is protected by Exemption 4 (CBI deleted copy) and a detailed, written justification to support protection of the designated information. Please note that if a document contains a portion of information that qualifies as exempt from disclosure, the entire document is not automatically exempt. The FOIA specifically provides that any reasonably segregable portions of a document must be provided to a requester after deletion of the portions that are exempt.

CONSULTATION RESPONSE

If you are responding to a consultation request, please enclose a copy of the records indicating all information you believe should be redacted under the FOIA as well as a brief justification to support withholding of that information.

You should submit your response no later than **December 30, 2015**, to the **AR Review Coordinator** at:

Mailing Address:

Animal and Plant Health Inspection Service
Legislative and Public Affairs
4700 River Road, Unit 50
Riverdale, Maryland 20737-1232

Phone: 301-851-4102

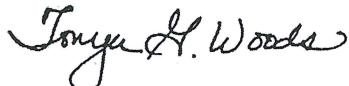
Fax: 301-734-5941

Please provide the name and contact information for the individual responsible for reviewing the Agency's final determination and include your facility name and registration number on all documents and correspondence. Your response must be sent to the address above as the AC staff will not be responsible for forwarding CBI responses to the FOIA office. APHIS will consider

your response carefully in making a final determination. Should the Agency decide to release any of the information, we will advise you in writing before a disclosure takes place and will provide your organization with an opportunity to seek judicial intervention.

If you have any questions, you may call the APHIS FOIA/PA office at (301) 851-4102 and ask to speak with the 2015 AR Coordinator.

Sincerely,



Tonya G. Woods
Director
Freedom of Information & Privacy Act
Legislative and Public Affairs

Enclosures:
1. Instructions for CBI Justification

To:	2015 AR Coordinator	From:
Facility Name:	Facility Reg. No.:	
Facility Fax:	No. of Pages:	
Facility Phone:	Date:	

NO OBJECTIONS RESPONSE

- We have no objections to the release of our Annual Report Attachments as received and do not intend to seek judicial review to bar release of our facility's Annual Report of Research Facility Column E Explanation(s) and/or Exception(s).

REDACTIONS PURSUANT TO EXEMPTION 4 REQUESTED

- We have objections to the release of our Annual Report Attachments as received and ask that you consider the enclosed justification statement and suggested redactions.

Signature

Date

Print Name (if different from above)

INSTRUCTIONS FOR CONFIDENTIAL BUSINESS INFORMATION(CBI) JUSTIFICATION

The justification is a two-part document and should be submitted in the format below or on the enclosed form. The language used to prepare your justification should be in non-technical terms when possible. Maintain the documents in the order provided and do not remove any documents. The FOIA Office will make a final decision as to whether the information qualifies for protection under the FOIA.

FORMAT

I. Introduction

Provide general information describing the competitive market of your business. Include any background information, which provides relevancy to comments used in your justification. If any information belongs to cooperating businesses, include a discussion of how information is maintained confidential, i.e., secrecy agreements.

II. In Your Justification, Categorize Like Pieces of Information

- A. Review the documents (e.g. permits/notifications, outlines of productions, efficacy/potency/safety test reports, technical/business proposals, etc.) we have referred to your organization for review under Executive Order 12600.
- B. Highlight the information your company has claimed as CBI
- C. Categorize like pieces of information (gene description, bacterin strain, production/research methods, testing results, financial information, cooperators, etc.) that can be easily identified
- D. Provide a discussion for each category identified. The discussion should describe:
 1. What each category of information reveals about your organization's business
 2. How a competitor could use this information to cause your company competitive harm
 3. The specific competitive harm (e.g., financial, research & development, etc.) that could result if the information is released. Essential for our release determination

III. Summary

Summarize the importance of the information that you have identified as CBI to the viability of your company's business operations. Provide the name and telephone number of a company official who should be contacted for further information.

IV. Documents

In your explanation package, you must provide a copy of all pages on which you are requesting redactions. You must clearly designate all information you believe should be withheld. Information can be designated by drawing a box around it or underlining it if

you are sending your submission by facsimile or email. Please use a writing instrument that is capable of drawing a dark heavy line to ensure your redactions can be seen. The underlined/boxed information must be visible through the markings. If sending by mail, you may highlight the information or use one of the methods previously listed.

V. Index (Optional)

Provide an index of the referred documents that your company designated as containing CBI. The index should match each appropriate categorical justification to the documents containing information claimed as CBI.

VI. Additional Help

For assistance in preparing your response or for more information regarding this process, please consult the following resources:

- A. Freedom of Information Act, 5 U.S.C. § 552
- B. Handling Information from a Private Business, 7 C.F.R. 1.12 (copy enclosed)
- C. Department of Justice's Guide to the FOIA at <http://www.justice.gov/oip/doj-guide-freedom-information-act-0>
- D. Executive Order 12,600 - Predisclosure Notification Procedures for Confidential Commercial Information (copy enclosed)
- E. List of Items That Are Not CBI (copy enclosed)
- F. Obtain the advice of counsel to ensure you provide the level of detail required to support any Exemption 4 assertions

NOTE - When documents contain information that qualifies as exempt from disclosure, the entire document is not necessarily exempt. The FOIA specifically provides that any reasonably segregable portions of a document must be provided to a requester after deletion of the portions that are exempt.

Code of Federal Regulations

Title 7 - Agriculture

Volume: 1

Date: 2010-01-01

Original Date: 2010-01-01

Title: Section 1.12 - Handling information from a private business.

Context: Title 7 - Agriculture. Subtitle A - Office of the Secretary of Agriculture. PART 1 - ADMINISTRATIVE REGULATIONS. Subpart A - Official Records.

§ 1.12 Handling information from a private business.

Each USDA agency is responsible for making the final determination with regard to the disclosure or nondisclosure of information in agency records that has been submitted by a business. When, in the course of responding to an FOIA request, an agency cannot readily determine whether the information obtained from a person is privileged or confidential business information, the policy of USDA is to obtain and consider the views of the submitter of the information and to provide the submitter an opportunity to object to any decision to disclose the information. If a request (including a subpoena duces tecum as described in § 1.215) is received in USDA for information that has been submitted by a business, the agency shall:

- (a) Provide the business information submitter with prompt notification of a request for that information (unless it is readily determined by the agency that the information requested should not be disclosed or, on the other hand, that the information is not exempt by law from disclosure). Afford business information submitter reasonable time in which to object to the disclosure of any specified portion of the information. The submitter must explain fully all grounds upon which disclosure is opposed. For example, if the submitter maintains that disclosure is likely to cause substantial harm to its competitive position, the submitter must explain item-by-item why disclosure would cause such harm. Information provided by a business submitter pursuant to this paragraph may itself be subject to disclosure under FOIA;
- (b) Notify the requester of the need to inform the submitter of a request for submitted business information;
- (c) Determine whether the requested records are exempt from disclosure or must be released;
- (d) Provide business information submitters with notice of any determination to disclose such records prior to the disclosure date, in order that the matter may be considered for possible judicial intervention; and
- (e) Notify business information submitters promptly of all instances in which FOIA requesters bring suit seeking to compel disclosure of submitted information.

[65 FR 46339, July 28, 2000]

Executive Order 12600--Predisclosure notification procedures for confidential commercial information

Source: The provisions of Executive Order 12600 of June 23, 1987, appear at 52 FR 23781, 3 CFR, 1987 Comp., p. 235, unless otherwise noted.

By the authority vested in me as President by the Constitution and statutes of the United States of America, and in order to provide predisclosure notification procedures under the Freedom of Information Act concerning confidential commercial information, and to make existing agency notification provisions more uniform, it is hereby ordered as follows:

Section 1. The head of each Executive department and agency subject to the Freedom of Information Act shall, to the extent permitted by law, establish procedures to notify submitters of records containing confidential commercial information as described in section 3 of this Order, when those records are requested under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, if after reviewing the request, the responsive records, and any appeal by the requester, the department or agency determines that it may be required to disclose the records. Such notice requires that an agency use good-faith efforts to advise submitters of confidential commercial information of the procedures established under this Order. Further, where notification of a voluminous number of submitters is required, such notification may be accomplished by posting or publishing the notice in a place reasonably calculated to accomplish notification.

Sec. 2. For purposes of this Order, the following definitions apply:

(a) "Confidential commercial information" means records provided to the government by a submitter that arguably contain material exempt from release under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4), because disclosure could reasonably be expected to cause substantial competitive harm.

(b) "Submitter" means any person or entity who provides confidential commercial information to the government. The term "submitter" includes, but is not limited to, corporations, state governments, and foreign governments.

Sec. 3. (a) For confidential commercial information submitted prior to January 1, 1988, the head of each Executive department or agency shall, to the extent permitted by law, provide a submitter with notice pursuant to section 1 whenever:

(i) the records are less than 10 years old and the information has been designated by the submitter as confidential commercial information; or

(ii) the department or agency has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.

(b) For confidential commercial information submitted on or after January 1, 1988, the head of each Executive department or agency shall, to the extent permitted by law, establish procedures to permit submitters of confidential commercial information to designate, at the time the information is submitted to the Federal government or a reasonable time thereafter, any information the disclosure of which the submitter claims could reasonably be expected to cause substantial competitive harm. Such agency procedures may provide for the expiration, after a specified period of time or changes in circumstances, of designations of competitive harm made by submitters. Additionally, such procedures may permit the agency to designate specific classes of information that will be treated by the agency as if the information had been so designated by the submitter. The head of each Executive department or agency shall, to the extent permitted by law, provide the submitter notice in accordance with section 1 of this Order whenever the department or agency determines that it may be required to disclose records:

(i) designated pursuant to this subsection; or

(ii) the disclosure of which the department or agency has reason to believe could reasonably be expected to cause substantial competitive harm.

Sec. 4. When notification is made pursuant to section 1, each agency's procedures shall, to the extent permitted by law, afford the submitter a reasonable period of time in which the submitter or its designee may object to the disclosure of any specified portion of the information and to state all grounds upon which disclosure is opposed.

Sec. 5. Each agency shall give careful consideration to all such specified grounds for nondisclosure prior to making an administrative determination of the issue. In all instances when the agency determines to disclose the requested records, its procedures shall provide that the agency give the submitter a written statement briefly explaining why the submitter's objections are not sustained. Such

statement shall, to the extent permitted by law, be provided a reasonable number of days prior to a specified disclosure date.

Sec. 6. Whenever a FOIA requester brings suit seeking to compel disclosure of confidential commercial information, each agency's procedures shall require that the submitter be promptly notified.

Sec. 7. The designation and notification procedures required by this Order shall be established by regulations, after notice and public comment. If similar procedures or regulations already exist, they should be reviewed for conformity and revised where necessary. Existing procedures or regulations need not be modified if they are in compliance with this Order.

Sec. 8. The notice requirements of this Order need not be followed if:

- (a) The agency determines that the information should not be disclosed;
- (b) The information has been published or has been officially made available to the public;
- (c) Disclosure of the information is required by law (other than 5 U.S.C. 552);
- (d) The disclosure is required by an agency rule that (1) was adopted pursuant to notice and public comment, (2) specifies narrow classes of records submitted to the agency that are to be released under the Freedom of Information Act, and (3) provides in exceptional circumstances for notice when the submitter provides written justification, at the time the information is submitted or a reasonable time thereafter, that disclosure of the information could reasonably be expected to cause substantial competitive harm;
- (e) The information requested is not designated by the submitter as exempt from disclosure in accordance with agency regulations promulgated pursuant to section 7, when the submitter had an opportunity to do so at the time of submission of the information or a reasonable time thereafter, unless the agency has substantial reason to believe that disclosure of the information would result in competitive harm; or
- (f) The designation made by the submitter in accordance with agency regulations promulgated pursuant to section 7 appears obviously frivolous; except that, in such case, the agency must provide the submitter with written notice of any final administrative disclosure determination within a reasonable number of days prior to the specified disclosure date.

Sec. 9. Whenever an agency notifies a submitter that it may be required to disclose information pursuant to section 1 of this Order, the agency shall also notify the requester that notice and an opportunity to comment are being provided the submitter. Whenever an agency notifies a submitter of a final decision pursuant to section 5 of this Order, the agency shall also notify the requester.

Sec. 10. This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

[Contact Us](#) [Accessibility](#) [Privacy Policy](#) [Freedom of Information Act](#) [No FEAR Act](#) [USA.gov](#)

The U.S. National Archives and Records Administration

1-86-NARA-NARA or 1-866-272-6272

LIST OF ITEMS THAT ARE NOT CBI

- Correspondence dates
- Business telephone numbers, including fax machines
- Legend lines in correspondence
- Expiration dates of serials
- Agency stop sale orders
- Final Agency decisions
- Approved labels and inserts
- Names of company officials, including manager of regulatory affairs
- Federal employee names
- State employee names
- APHIS date stamp
- Names of tests required in accordance with CFR, except when options apply
- Test results reported in column E of APHIS Form 2008
- The number designations for tables and figures referenced as an enclosure
- Published articles, including dates and volume numbers
- Irrelevant non-CBI information contained in a responsive document
- References to numbered outlines, protocols, or permits
- Required CFR citations, except when options apply
- Outline of Production headings published in the CFR
- Names of regulated or licensed products, product codes, and firm numbers
- Submission dates on outlines, permits, applications, transmittal forms, etc.
- Funding dollar amounts to cover the costs of government services
- Dollar amounts of awarded government contracts
- Locations of company owned field test sites
- Typist initial on company correspondence
- Product serial numbers, except for comprehensive list of numbers

Please note that there may be exceptions to this list depending on the written justification submitted. Also, some items on this list may be withheld pursuant to another FOIA exemption (see enclosed list of FOIA exemptions).

List of 9 Freedom of Information Act Exemptions

The Freedom of Information Act entitles the following exemptions on documents being requested by the public:

1. Those documents properly classified as secret in the interest of national defense or foreign policy;
2. Related solely to internal personnel rules and practices;
3. Specifically exempted by other statutes;
4. A trade secret or privileged or confidential commercial or financial information obtained from a person;
5. A privileged inter-agency or intra-agency memorandum or letter;
6. A personnel, medical, or similar file the release of which would constitute a clearly unwarranted invasion of personal privacy;
7. Compiled for law enforcement purposes, the release of which
 - a. could reasonably be expected to interfere with law enforcement proceedings,
 - b. would deprive a person of a right to a fair trial or an impartial adjudication,
 - c. could reasonably be expected to constitute an unwarranted invasion of personal privacy,
 - d. could reasonably be expected to disclose the identity of a confidential source,
 - e. would disclose techniques, procedures, or guidelines for investigations or prosecutions, or
 - f. could reasonably be expected to endanger an individual's life or physical safety;
8. Contained in or related to examination, operating, or condition reports about financial institutions that the SEC regulates or supervises; or
9. And those documents containing exempt information about gas or oil wells.