#254

Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products

Guidance for Industry

This version of the guidance replaces the version made available in October 2022. This document has been revised to update an address and add an Equine virus to Appendix A.

Submit comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2021-D-0401.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr, College Park, MD 20740, and may be viewed on the Internet at https://www.fda.gov/animal-veterinary, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
February 2026

Table of Contents

Contains Nonbinding Recommendations

Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is for sponsors, firms, individuals, and establishments that participate in the manufacture of, or perform any aspect of the donor eligibility determination for animal cells, tissues, and cell- and tissue-based products (ACTPs). ACTPs that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or ACTPs intended to affect the structure or function of the animal generally meet the definition of a new animal drug.[1] All new animal drugs, including ACTPs, are required to be manufactured in accordance with Current Good Manufacturing Practice (CGMP) to ensure that such drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as to safety, and have the identity, strength, quality, and purity characteristics which they purport to or are represented to possess.[2] Donor eligibility is critical to ensuring safety and quality when manufacturing allogeneic or xenogeneic ACTPs. A donor of allogeneic or xenogeneic ACTPs should be considered eligible to donate only if screening of the donor shows that the donor is healthy and free from risk factors for, and clinical evidence of, infection with relevant disease agents and diseases, and the donor (and product/source material) test results for relevant disease agents are negative or nonreactive.

The Food and Drug Administration (FDA, or we) encourages sponsors and manufacturers of ACTPs (you) to contact CVM early in product development to discuss considerations specific to the manufacture and approval of your new animal drug product.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

[1] Section 201(v) of the FD&C Act [21 U.S.C. § 321(v)] defines a "new animal drug", in part, as any drug intended for use for animals that is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling.

[2] See section 501(a)(2)(B) of the FD&C Act [21 U.S.C. § 351(a)(2)(B)]

II. BACKGROUND

Advances in the field of veterinary regenerative medicine have resulted in increasing research into veterinary applications for ACTPs, and many of these products are intended for use as new animal drugs.

In this guidance, ACTPs mean those articles containing, consisting of, or derived from cells or tissues that are intended for implantation, transplantation, infusion, transfer, or other means of administration to an animal recipient. In this guidance, the term ACTP refers only to those products subject to regulation under the FD&C Act. ACTPs include cell-based products and animal stem cell-based products as defined in Guidance for Industry (GFI) #218, "Cell-Based Products for Animal Use" (July 2015).[3]

This guidance offers FDA's recommendations for those aspects of manufacturing related to determining donor eligibility for ACTPs. There are both statutory and regulatory requirements for CGMP. The CGMP statutory requirements are found in section 501(a)(2)(B) of the FD&C Act. The CGMP regulatory requirements are found in Title 21 of the Code of Federal Regulations, parts 210 and 211.

As noted in GFI #253, "Current Good Manufacturing Practice for Animal Cells, Tissues, and Cell- and Tissue-Based Products" (October 2022),[4] FDA recognizes that the manufacture of ACTPs presents unique considerations for complying with regulatory CGMP including donor eligibility determinations. Establishments may use an alternative approach if it satisfies the requirements of section 501(a)(2)(B) of the FD&C Act and applicable regulations.

Selecting appropriate donors is critical to ensuring the safety, identity, strength, quality, and purity of the resulting product. This guidance addresses appropriate methods and considerations for determining donor eligibility for ACTPs intended for use as new animal drugs. Establishments performing any function related to donor eligibility should comply with the CGMP related to that function.

III. PURPOSE AND SCOPE

To prevent transmission of disease when manufacturing ACTPs, it is necessary to determine that donors are healthy and free from relevant disease agents (see section IV.C. *Relevant Disease Agents* for the definition of relevant disease agents). Transmission of relevant disease agents by an ACTP can result from the presence of relevant disease agents in the donated cells/tissues (either within the cells/tissues, within other accompanying cells/tissues, or in the extracellular components of the product).

This guidance provides recommendations for determining that a donor is healthy and free from relevant disease agents and is an eligible source of cells, tissues, or both, used in the manufacture of allogeneic or xenogeneic ACTPs. The recommendations in this guidance are intended to help

[3] https://www.fda.gov/media/88925/download

[4] https://www.fda.gov/media/147150/download

manufacturers of ACTPs ensure product safety and comply with the statutory and applicable regulatory CGMP requirements for the manufacture of new animal drugs.

This guidance applies to sponsors, firms, individuals, and establishments that participate in the manufacture of ACTPs and perform any aspect of donor eligibility determination.

IV. DONOR ELIGIBILITY DETERMINATION

A. General

The donor eligibility determination is a conclusion, based on donor screening and testing results, that a donor is either eligible or ineligible to donate cells or tissues for use in the manufacture of an ACTP. The donor eligibility determination ensures that the donor is healthy and free from risk factors for, and clinical evidence of, relevant disease agents and diseases.

A donor eligibility determination should be completed for each donation of cells or tissues used in the manufacture of an ACTP. This includes all components of the ACTP of human or animal origin. In general, the donor eligibility determination should be performed for the individual donor. In the case of embryonic or fetal donations, a donor eligibility determination should be performed for both the oocyte donor and semen donor (and surrogate dam, if appropriate). In the case of a closed group of animals, it may be possible to perform a donor eligibility determination for the entire group.

The donor eligibility determination should be made by a person with appropriate training and qualifications, including adequate knowledge of applicable Federal regulations and guidance. All information contributing to the donor eligibility determination should be documented and attributable to the person providing the information. For example, a physical examination of a potential donor animal should be performed by a veterinarian. The veterinarian should record the results of the examination, and sign and date the record. The veterinarian's training and qualifications should also be documented.

A donor should be considered eligible only if screening of the donor shows that the donor is healthy and free from risk factors for, and clinical evidence of, infection with relevant disease agents and diseases, and the donor (and product/source material) test results for relevant disease agents are negative or nonreactive.

An ACTP should not be implanted, transplanted, infused, or transferred, until the donor has been determined to be eligible.

B. Submitting Donor Selection Criteria and Donor Eligibility Determinations to CVM

There are two occasions when you should submit information relating to donor eligibility to CVM:

- Donor selection criteria

You should submit your process and criteria for selecting donors to CVM for review early in the development process (before donors are selected). This early submission should include items 1 through 6 from the list below. Data collection forms associated with item 7 and considerations associated with item 10 should also be included in the submission. Your process and criteria for selecting donors should be submitted to the donor eligibility module of the product characterization technical section of your Investigational New Animal Drug (INAD) file.

A risk-based, product-specific approach should be used to determine the selection criteria for eligible donors. The selection criteria should consider the characteristics of the product, the intended recipient population, the donor population, and the risk of transmission of disease agents to both recipients and persons handling the ACTP. A combination of donor screening (historical and clinical information), donor testing (testing the donor for specific disease agents), and testing of the donated cells/tissue or product for specific disease agents should be used to demonstrate the absence of a disease agent in the donor. For example, when donor screening information is not sufficient to ensure absence of a disease agent, testing of the donor or donated cells/tissues or product should be performed. In combination with a comprehensive donor screening program, the most sensitive test method for detecting a disease agent should be utilized.

- Donor eligibility determination

After you have determined a donor to be eligible, you should submit the data supporting the donor eligibility determination to CVM for review prior to approval of the ACTP containing cells or tissue from that donation. This submission should include items 6 through 10 from the list below, as well as any changes, deviations from, or new information pertaining to items 1 through 6. The donor eligibility determination for donors of cells and tissues used to manufacture product that is the subject of an original new animal drug application may be submitted to the donor eligibility module of the product characterization technical section. Donor eligibility determinations for new donations occurring after the original application is approved should be submitted as part of the prior-approval supplement supporting approval of the new cell line or source material.

Information submitted to CVM in support of donor eligibility should include the following:

1. A list of relevant disease agents for your ACTP (see section IV.C. *Relevant Disease Agents*);
2. Your standard operating procedure(s) (SOP) or protocol for determining donor eligibility, including the specific criteria for determining a donor to be eligible;
3. Donor screening methods (see section IV.D. *Donor Screening*);

4. Testing methods for testing of the donor and donated cells/tissues or product (see section IV.E. *Donor Testing*);
5. Justifications, as needed, for inclusion/exclusion of agents from the list of relevant disease agents, donor screening, and testing methods and eligibility criteria;
6. Qualifications and training of the person responsible for determining donor eligibility;
7. Documentation for donor screening, testing, and donor eligibility determination, including all data collection forms and raw data;
8. Test method validation;
9. The final report of donor eligibility determination, including donor screening and testing results and interpretation of the results (see section IV.F. *Final Donor Eligibility Determination*); and
10. Any additional information impacting the donor eligibility determination, including any additional species or product specific considerations, or deviations from procedures.

C. Relevant Disease Agents

1. Definition

In this guidance, the term "relevant disease agent" means any transmissible agent, for which appropriate screening and/or testing measures exist, meeting any of the following conditions:

- A disease agent that is potentially transmissible to the recipient of the ACTP, to other animals in contact with the recipient of the ACTP, or to people who may handle or come in contact with the ACTP, and:
  - The disease agent has a sufficient incidence or prevalence to support a risk of its presence in the donor population; or
  - The disease agent may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection.
- A disease agent that could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention.
- A disease agent that is reportable to the United States Department of Agriculture, World Organization for Animal Health (OIE), or local government in the appropriate jurisdiction.
- A disease agent that may affect the safety of edible tissues (for human or animal consumption) derived from food-producing animals treated with the ACTP.

2. List of relevant disease agents

As part of the donor selection criteria, you should develop a comprehensive list of relevant disease agents under consideration for your ACTP. This is the list of agents to consider when determining which screening and testing procedures are appropriate. All factors described in the section above (see section IV.C.1. *Definition*) should be considered when determining if a disease agent is relevant.

Lists of relevant disease agents for the dog, cat, and horse are included in Appendix A. The lists are intended only as a guide for donor animals residing in the United States and are not comprehensive. Additional disease agents may need to be considered for most ACTPs based on the donor species, donor selection criteria, availability of information on the donor population, tissue source and other characteristics of the ACTP, the manufacturing process, the intended recipient population, and indication. For example, additional relevant disease agents may exist for donors with a travel history to, or residing in, regions endemic for specific disease agents not included on the list in Appendix A (e.g., travel or residence outside the United States).

Sponsors of all ACTPs are encouraged to submit their donor selection criteria, including a list of relevant disease agents for their ACTP, to CVM for review early in the development process. Sponsors using donor species other than the dog, cat, or horse, and sponsors developing ACTPs for use in food-producing animals, are encouraged to contact CVM to discuss relevant disease agents prior to submitting their donor selection criteria.

D. Donor Screening

Donor screening should evaluate the donor's general health and risk of exposure to relevant disease agents. Donor screening should include both historical and clinical assessments of the donor to help prevent the introduction, transmission, or spread of diseases and to help ensure ACTP quality.

1. Donor screening information and evaluations

   Donor screening should include assessment of historical information and clinical evaluations. At a minimum, you should have procedures for, and documentation of, the following information for each animal donor:

   - Historical Information
     - Description of the donor (e.g., this may include the source of the animal, identification, signalment, and ownership history);
     - Detailed medical history;
     - Detailed travel history;
     - Detailed vaccination history;

- Detailed description of environmental and social history (e.g., this may include a description of housing, management, exposure to other animals, movement of new animals onto the premises, exposure to wildlife, food and food source); and
- Requirements for eligibility based on historical information.

- Clinical Evaluations
  - Physical examinations, including an assessment of each body system and temperature, pulse, and respiration;
  - Clinical pathology;
  - Daily health observations;
  - Species-specific appropriate general health screening tests (e.g., fecal exam, heartworm test);
  - Procedures to reduce the risk of exposure to disease agents during the peridonation period (e.g., quarantine, restrictions on travel, restrictions on introduction of new animals); and
  - Requirements for eligibility based on screening evaluations and procedures

2. Donor screening considerations

   You should establish a peridonation period. The peridonation period is the time during which a potential animal donor is observed for signs of clinical disease. The peridonation period should include a time period both before and after donation sufficient to assess the donor for signs of recent disease or incubating disease agents. The duration of the peridonation period is based on the incubation period of relevant disease agents, as well as the product-specific historical and screening requirements for donors. For example, the peridonation period for a donor from a pathogen-free, closed colony of dogs may be shorter than that for a client-owned pet dog.

   Procedures to reduce the risk of exposure to relevant disease agents (e.g., restrictions on travel, exposure to new animals, and exposure to wildlife) and to evaluate the general health of animal donors should occur throughout the peridonation period.

   All animal donors should be evaluated by a veterinarian[5] and determined to be clinically healthy throughout the peridonation period such that the donor has no condition or characteristic that could impact the quality of the ACTP. In general, a healthy animal donor has a state of wellbeing such that the animal has normal body function, productivity, and behavior, and absence of disease, and the environmental, behavioral, and nutritional needs of the animal are met. An animal may be determined to be healthy in the presence of minor localized injuries or lesions (minor

[5] Veterinarians should hold a license or equivalent credentials as required by the locale in which they practice veterinary medicine.

contusions, lacerations, burns, etc.) that are not associated with body temperature elevation or pain and distress. The health of an animal donor should be based on evaluations, including, but not limited to, physical exams, clinical pathology, and species-specific appropriate tests. At a minimum, these evaluations and tests should be performed at the beginning and end of the peridonation period, as well as at the time of donation. Multiple veterinarians may perform these evaluations. However, there should be a single individual responsible for making the donor eligibility determination (see Section IV.F.).

In general, eligible animal donors should be required to survive the peridonation period. If a potential animal donor dies or is euthanized prior to the end of the peridonation period for reasons that do not increase the risk of exposure to relevant disease agents (such as trauma), a complete and thorough necropsy should be performed, cause of death should be determined, the health of other animals on the premises should be assessed, and the donor animal should be tested for all possible relevant disease agents (those listed in Appendix A, as well as any other agents specific to the donor animal's environment and history). If the donation is intended to take place after the animal is deceased (for example, the donor is a healthy food-producing animal and the donated sample will be recovered at slaughter, or the donor is a research animal where donation will occur after euthanasia), procedures to collect all relevant postmortem health information at the slaughter or research facility should be reviewed by CVM and in place prior to the time of donation.

Historical information (medical, travel, vaccination, production, and environment) should be obtained and documented for a period long enough to assure absence of exposure to relevant disease agents resulting in chronic illness or latent infections. In cases where sufficient historical information is not available, donor screening and testing evaluations should be designed to ensure absence of chronic and/or latent relevant disease agents.

We recommend developing robust donor screening criteria, as there may be limitations associated with testing for certain relevant disease agents. For example, some donor tests may be validated for use as a diagnostic test but not as a screening test in a healthy animal. In this situation, the diagnostic test alone may not be sufficient to determine the donor is free from risk factors for, or clinical evidence of infection with the relevant disease agent. However, in some circumstances, you may use robust screening criteria in combination with the diagnostic test to help support donor eligibility.

E. Donor Testing

1. Determining When to Test for a Disease Agent

The presence of an agent on the list of relevant disease agents in Appendix A does not mean that a test for that agent must be carried out. However, if not performing a test for a relevant disease agent listed in Appendix A, you should provide justification based on a risk assessment.

In general, donors or the donated cells/tissues or product should be tested for all relevant disease agents for which screening information cannot rule out exposure to, or presence of, the relevant disease agent. If not performing testing for a relevant disease agent, your donor eligibility determination process should specifically state which screening criteria justify the absence of that agent.

The following are examples of justification for not testing for a relevant disease agent:

- Disease/agent does not occur in the donor's geographic location and the donor and donated material could not have been contaminated by this agent after donation. Conclusive supporting official documented evidence should be provided (e.g., current OIE status).
- Disease/agent does not occur in the colony/herd of origin (i.e., specific pathogen-free status). Supporting documentary evidence should be provided for monitoring with serological and/or agent detection methods, accompanied by strict biosecurity measures.
- Material cannot be contaminated with this agent (e.g., agent does not cross the placenta or agent is localized to a tissue not included in the donation). Strong justification should be provided, such as evidence generated from the specific disease agent in the donor species (i.e., literature from similar disease agents or other species is generally insufficient). For example, it is possible to prove that an agent regularly crosses the placenta, but it is more difficult to prove that an agent may never cross the placenta. In this example, data evaluating the inability of the specific disease agent to cross the placenta in the donor species could be provided as justification.
- The agent cannot survive the manufacturing process (e.g., the agent is inactivated using a validated method or is removed by the production process).
- The agent will be identified by sterility testing as conducted per United States Pharmacopeia (USP) Chapter <71> *Sterility Tests*[6] or equivalent test (e.g., the agent is an aerobe, anaerobe, or fungi).

2. Test Methods

All test methods should be validated. The parameters to be validated in each case should be chosen in agreement with the purpose of the assay. You should refer to the appropriate USP chapter for additional information on test method validation. We recommend submitting your test method validation early in the development process.

You should utilize the most accurate and sensitive test method available for each agent. Testing should be performed on the donor, donated cells/tissues or product,

[6] http://ftp.uspbpep.com/v29240/usp29nf24s0_c71.html

whichever is most likely to identify the disease agent. The specimen for testing should be collected, handled, and shipped according to standards set by the laboratory performing the test.

For the detection of viruses, appropriate methods for virus isolation and identification should be used (cell cultures, embryonated eggs, animal inoculation) and criteria established (e.g., cytopathic effect, hemadsorption, immunostaining, etc.). The sensitivity of the test for specified agents should be known, not only for laboratory adapted strains, but also for field (wild) strains. Antigen and genome detection methods (e.g., PCR) can also be used. The specificity of the test should be known (e.g., group or type specific).

Sterility testing should be performed on all ACTPs. Specific bacterial testing should be performed for bacteria that are not detectable by the sterility test, such as mycobacteria, mycoplasmas, and obligatory intracellular bacteria.

Detection of an agent may also be based on detection of corresponding antibodies using appropriate serological methods.

When choosing a contract laboratory to conduct relevant disease agent testing, we recommend that you consider the quality of the practices and procedures used by the laboratory (e.g., accreditations, availability of SOPs, review validation reports, etc.). Test methods should be validated and submitted to CVM for review.

3. Donor testing information

Donor testing information should include, at a minimum, procedures for and documentation of:

- Tests performed, including justification for the choice of test;
- Sample to be tested;
- Date/timing of sample collection;
- Sample handling;
- Laboratory performing the test;
- Criteria for interpreting test results;
- Test method validation;
- Documentation of results; and
- Requirements for eligibility based on testing.

Donors should be considered eligible only if they have negative or nonreactive test results. The donor selection criteria submitted to CVM should clearly define negative or nonreactive test results for each test and provide justification for the acceptability of those results where applicable. The testing laboratories may provide the

acceptable limits or cut off values for their tests. You should further describe how you will interpret the results. Interpretation of test results should be based on your specific donor selection criteria and product characteristics. For example, serologic tests results should be interpreted based on donor and donor population characteristics, such as vaccination status. Test method validation may be submitted with the donor selection criteria or with the final donor eligibility determination report.

All results from testing of the donor and donated cells/tissues or product should be available prior to making the final donor eligibility determination.

F. Final Donor Eligibility Determination

The final donor eligibility determination should be made by a responsible person who has appropriate training, qualifications, and authorization. This person should review all records related to the donor's eligibility status[7] and determine and document the eligibility of the donor.

A donor should be considered eligible if:

- Donor screening and testing are conducted in a manner consistent with CGMP, and donor screening and testing addresses the considerations described in this guidance;
- Donor screening indicates that the donor is healthy and free from risk factors for, and clinical evidence of, infection due to relevant disease agents and diseases; and
- The results of donor and donated cells/tissues and product testing for relevant disease agents are negative or nonreactive.

A final report should be created for each donor eligibility determination. The final report should include:

- Requirements for donor eligibility (donor selection criteria);
- Documentation of donor screening and testing results;
- Interpretation of donor screening and testing results;
- A final statement of the eligibility (or lack of eligibility) of the donor;
- Deviations from the donor selection criteria process; and
- Qualifications of the person responsible for making the donor eligibility determination.

[7] In addition to donor screening and testing procedures and results, these records may include reports regarding disease outbreaks, additional donor medical records, and any other information necessary to determine that the donor is healthy and free from risk factors for, and clinical evidence of, relevant disease agents and diseases, and that donor test results for relevant disease agents are negative.

The final report and all raw data and documentation supporting the determination of donor eligibility, including validation of test methods, should be submitted to CVM in support of approval of the ACTP containing donated cells/tissue from each individual donation event.

V. PROCEDURES

Any sponsors, firms, individuals, and establishments involved in determining donor eligibility should establish and maintain procedures for all steps they perform in testing, screening, determining donor eligibility, and complying with all other applicable CGMP. That is, procedures should be defined, documented (in writing or electronically), and implemented; then followed, reviewed, and revised as needed on an ongoing basis. All procedures should be reviewed and approved by a qualified person before implementation.

Procedures for any operations should be readily available to the personnel in the area where the operations are performed, or in a nearby area if such availability is impractical.

Any departures from established procedures and the justifications for those departures should be recorded at the time of occurrence. ACTPs recovered from a donor whose eligibility is determined under a departure from procedures should not be made available for release unless the person responsible for determining donor eligibility has determined that the departure does not increase the risk of disease transmission with use of the ACTP.

See GFI #253, section VII. *Procedures* for additional recommendations related to procedures.

VI. DONOR TRACKING

If you perform any step in the manufacture of an ACTP during which you handle the donor cells/tissues, or product, you should track each ACTP. A system should be in place to track all ACTPs from the donor through final distribution. The system should also be able to track a specific product back to the donor.

Each donor should be assigned a distinct identification code. Donor cells or tissues should be identified by the distinct identification code from the time of donation, throughout all steps of the manufacturing process, and through final distribution of the ACTP. The distinct identification code should be affixed to the ACTP container for both investigational and approved ACTPs.

See GFI #253, section XIX. *Tracking* for additional recommendations related to tracking.

VII. RECORDS

See GFI #253, section XVIII. *Records* for additional recommendations related to records.

A. Record maintenance and retention

The following records related to donor eligibility determinations should be maintained:

- The final donor eligibility determination report;
- Results and interpretation of all testing for relevant disease agents;
- Results and interpretation of all donor screening evaluations and procedures;
- The name and address of the laboratory(ies) performing the tests;
- The name of the responsible person who made the donor eligibility determination;
- The date of the donor eligibility determination; and
- All other records supporting the donor eligibility determination.

All records should be attributable, legible, contemporaneous, original, and accurate. Information on the identity and relevant medical records of the donor should be in English or, if in another language, should be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document so that compliance with CGMP can be more easily determined by FDA.

All records relating to donor eligibility determination should be maintained and available for authorized inspection by or upon request from FDA. Records that can be readily retrieved from another location by electronic means are considered "retained." All records pertaining to a particular ACTP should be retained for at least 10 years after the date of the ACTP's distribution, disposition, or expiration, whichever is latest.[8]

B. Records accompanying the ACTP

Once the donor eligibility determination has been made, the following records should accompany the ACTP at all times:

- A distinct identification code affixed to the ACTP container that relates the ACTP to the donor and to all records pertaining to the ACTP;
- A statement that the donor has been determined to be eligible or ineligible.
  - For ineligible donors, the reason for ineligibility should be stated.
  - For ineligible donors, the ACTP should be clearly labeled as originating from an ineligible donor until and throughout destruction of the ACTP;
- A summary of the records used to make the donor eligibility determination, including a listing and interpretation of results for all relevant disease agents where donor testing was performed; and
- The name and address of the establishment that made the donor eligibility determination.

[8] The regulations in 21 CFR 211.180 require that records be kept for at least 1 year after expiration. However, we recognize that expiration of ACTPs varies from hours to an indefinite period of time for some cryopreserved ACTPs. Additionally, some forms of contamination or safety concerns may not be evident until years after the product is manufactured. For these reasons, we recommend a record retention period of at least 10 years.

VIII. QUARANTINE OF ACTPS

ACTPs should be kept in quarantine until completion of the donor eligibility determination. Quarantine means the storage or identification of an ACTP in a physically separate area clearly identified for such use, or through use of other procedures, such as automated designation in order to prevent improper release. Quarantined ACTPs should be clearly identified as such, and easily distinguishable from ACTPs available for release.

If you transport an ACTP before completion of the donor eligibility determination, you should keep it in quarantine during transport. Quarantined ACTPs should be accompanied by records:

- Identifying the donor by the distinct identification code affixed to the ACTP container;
- Stating that the donor eligibility has not been completed; and
- Stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination.

Quarantined ACTPs should not be distributed for clinical use (use in client-owned animals); however, quarantined ACTPs may be used for non-clinical laboratory studies (studies in non-client-owned animals) provided appropriate precautions are taken to prevent spread of any potential relevant disease agents beyond the laboratory. The immediate container (and all other labeling components) of quarantined ACTPs should be clearly labeled, "NOT FOR DISTRIBUTION: NOT EVALUATED FOR INFECTIOUS SUBSTANCES."

IX. ACTPS FROM INELIGIBLE DONORS

ACTPs from donors that have been determined to be ineligible should be stored or identified in a physically separate area clearly identified for such use, or follow other procedures, such as automated designation, that are adequate to prevent improper release until destruction or other disposition of the ACTP occurs.

ACTPs from ineligible donors should not be distributed for clinical use (use in client-owned animals); however, ACTPs from ineligible donors may be used for nonclinical laboratory studies (studies in non-client-owned animals) provided appropriate precautions are taken to prevent spread of any potentially relevant disease agents beyond the laboratory. The immediate container (and all other labeling components) of ACTPs from ineligible donors should be clearly labeled, "WARNING: NOT FOR DISTRIBUTION: RISK OF DISEASE TRANSMISSION." If the donor tested positive for a specific relevant disease agent, then all labeling components should contain the additional statement, "WARNING: Positive test results for [name of agent or disease]." If the product is distributed for a non-clinical use, the label should state, "For Nonclinical Use Only."

APPENDIX A

This appendix provides a sample list of relevant disease agents for dogs, horses, and cats residing in the United States. These lists are intended to be a guide and are not comprehensive. These lists focus on disease agents that may not be detected by sterility testing. For many ACTPs, additional relevant disease agents may need to be considered.

Dogs

Adenovirus
Bluetongue virus
Corona Virus
Distemper Virus
Herpes Virus
Influenza Virus
Oral Papilloma Virus
Parainfluenza Virus
Parvovirus
Rabies Virus
Swine Herpes Virus 1

Anaplasma spp
Babesia spp
Bartonella vinsonii
Borellia spp
Brucella canis
Erhlichia spp
Leishmania spp
Leptospira spp
Mycoplasma haemocanis
Neorickettsia spp
Neospora caninum
Rickettsia rickettsii
Trypanosoma cruzi
Dirofilaria immitis

Horses

Equine Adenovirus
Equine Encephalomyelitis Viruses
Equine Hepacivirus
Equine Herpes Virus (EHV-1, EHV-4)
Equine Infectious Anemia Virus
Equine Influenza Virus
Equine Parvovirus
Equine Rhinitis Virus A and B Equine
Rotavirus

Equine Viral Arteritis Virus
Rabies Virus
Vesicular Stomatitis Virus
West Nile Virus

Anaplasma phagocytophilia
Babesia caballi
Borellia spp
Neorickettsia risticii
Theileria equi

Cats

Feline Calicivirus
Feline Coronavirus/Feline Infectious Peritonitis virus
Feline Foamy virus
Feline Herpes virus
Feline Immunodeficiency Virus
Feline Leukemia Virus
Feline Panleukopenia
Rabies Virus
Swine Herpes Virus 1

Bartonella spp
Candidatus Mycoplasma haemominutum
Chlamydophila felis
Cytauxzoon felis
Mycoplasma haemofelis
Toxoplasma gondii