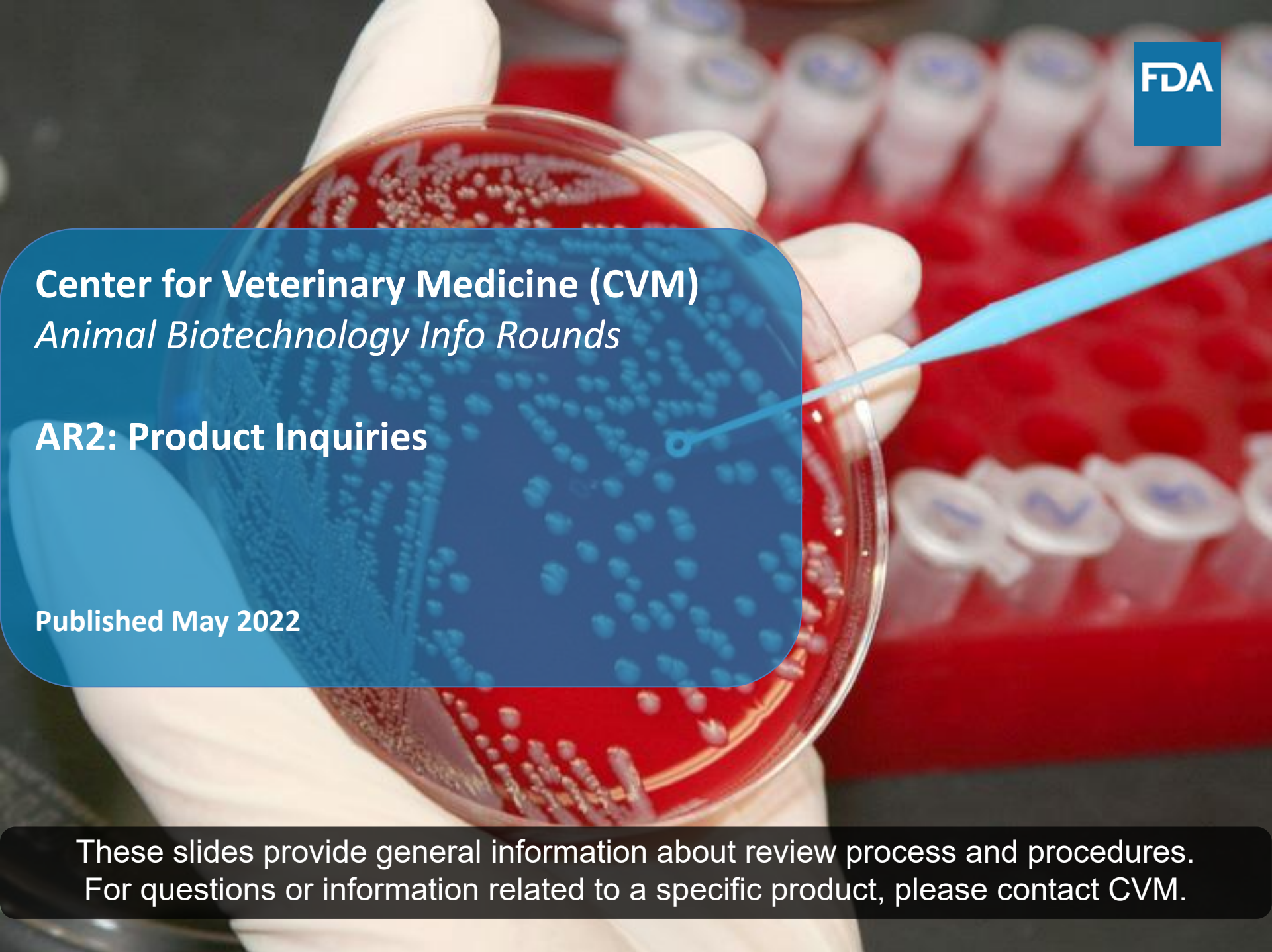


Center for Veterinary Medicine (CVM)

Animal Biotechnology Info Rounds

AR2: Product Inquiries

Published May 2022

These slides provide general information about review process and procedures. For questions or information related to a specific product, please contact CVM.

Purpose and Scope

This document addresses frequently asked questions regarding regulatory oversight of animal biotechnology products, including intentional genomic alterations (IGAs) in animals or animal cells, tissues, and cell- and tissue-based products (ACTPs).

This document is intended to help developers understand how to request a regulatory oversight determination (i.e., product inquiry) for animal biotechnology products as well as the process CVM uses to make this determination.

* Note: This document only applies to animal biotechnology products. Regulatory oversight for other product types may differ.

Outline

- Which federal agency regulates an animal biotechnology product?
- How and when should I contact CVM about an animal biotechnology product?
- What is the best way to format an animal biotechnology product inquiry?
- How long will it take to process the animal biotechnology product inquiry?
- Frequently asked questions and resources

Which federal agency regulates an animal biotechnology product?

FDA's oversight can be closely related to those of other federal agencies.

It may be challenging for sponsors to determine the appropriate federal agency to contact.

FDA regulates a wide range of products, including products that meet the definition of a food, drug, or medical device.

When CVM receives inquiries about an animal biotechnology product, the first step is to determine whether the product is one that CVM regulates, that CVM and another FDA Center regulates, or that another federal agency regulates.

How and when should I contact CVM about an animal biotechnology product?

CVM evaluates new inquiries concerning animal biotechnology products on a case-by-case basis to determine which agency has regulatory oversight.

- Contact the “Ask CVM” mailbox for any regulatory oversight inquiries
- Write to: AskCVM@fda.hhs.gov

Contact CVM early in the development of your product. CVM is flexible and approachable.

What is the best way to format an animal biotechnology product inquiry?

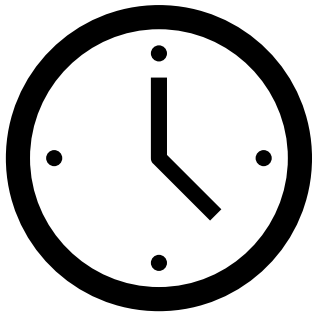
We ask that you write to AskCVM@fda.hhs.gov with the following minimum general information:

1. Requestor name/firm information,
2. Contact information of requestor,
3. Product description,
4. Claim/indication of the product,
5. Mechanism of action (to achieve intended use/indication), and
6. Any other pertinent information? (e.g., current project status, literature, proposed labeling, etc.).

How long will it take to process the animal biotechnology product inquiry?

The typical response time to process an animal biotechnology product inquiry is within 30 days. CVM's response time is impacted by several factors, including the following questions.

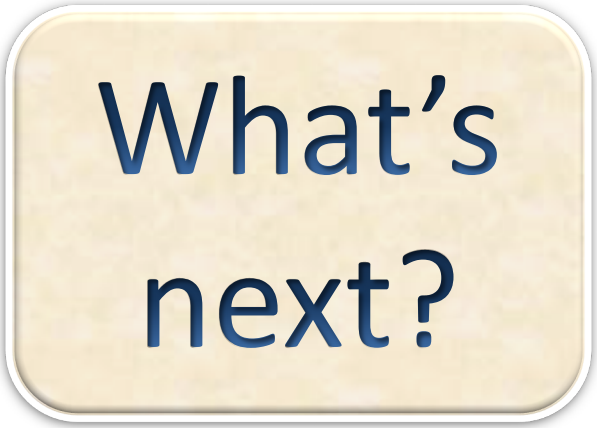
- Does the product use or is it produced by a novel technology?
- Was sufficient information about the product provided in the inquiry?
- Will another federal agency need to be consulted?



What should I expect next?

CVM will recommend the next steps:

- If the animal biotechnology product will not be regulated by CVM and another federal agency has jurisdiction, then CVM will recommend the appropriate federal agency to contact.
- If another FDA Center will regulate in addition to CVM, CVM will recommend the appropriate Center to contact.



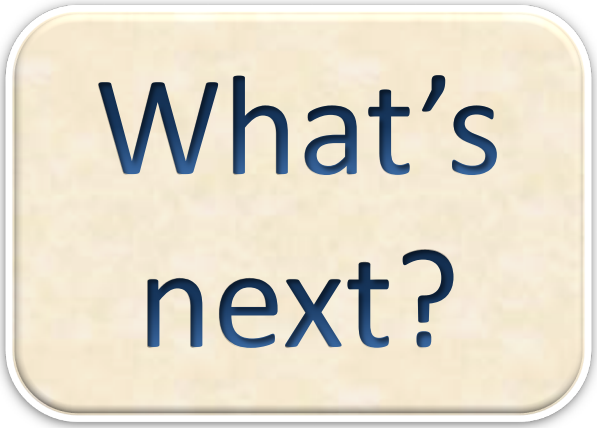
NOTE: If changes are made to the animal biotechnology product after your inquiry, the changes may impact which federal agency has regulatory oversight of the product.

What should I expect next?, cont'd

If the animal biotechnology product is regulated by CVM, then the next step is to communicate with a CVM Project Manager. The Project Manager will help you open a file and discuss the next steps in the process.

ONADE Project Management Team contact for animal biotechnology products:

CVM_PM_Biotech@fda.hhs.gov



You can find more information to help you get started in the animal biotechnology approval process in our other Animal Biotechnology Info Rounds.

Frequently Asked Questions

I am developing IGAs in animals to produce human biopharmaceuticals or medical devices…

…is the product also subject to regulation by other FDA Centers, and who do I contact?

CVM regulates the IGA in the animal and the appropriate FDA Center regulates the animal-derived product for human use (see examples below):

Center for Biologics Evaluation and Research (CBER)

E.g., human vaccines, tissues, cellular and gene therapies

Center for Drug Evaluation and Research (CDER)

E.g., cytokines, monoclonal antibodies

Center for Devices and Radiological Health (CDRH)

E.g., devices with tissue components

Center	Contact
CBER:	CBERProductJurisdiction@fda.hhs.gov
CDER:	CDERProductJurisdiction@fda.hhs.gov
CDRH:	CDRHProductJurisdiction@fda.hhs.gov

I am developing IGAs in animals to produce human biopharmaceuticals or medical devices …

…is the product also subject to regulation by other FDA Centers, and who do I contact?

There are two regulated articles: 1) the IGA(s) in the animal (subject to CVM's approval), and 2) the human product (subject to approval or clearance by the other FDA Center).

- NOTE: The animal product needs to be fully developed before review of the human product can be finalized.

CVM works closely with the other FDA Centers to ensure that oversight is complementary and not unnecessarily duplicative.

- For more information, see AR7: Collaborations between FDA Centers (https://www.fda.gov/media/152908/download)

I am developing IGAs in mosquitoes…

…who will regulate the product?

Environmental Protection Agency (EPA)

IGAs intended for population control

FDA CVM

IGAs intended for other uses, e.g., to control disease transmission, lower viral load

Document	Link
GFI #236:	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-236-clarification-fda-and-epa-jurisdiction-over-mosquito-related-products
Draft GFI #187:	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-187-regulation-intentionally-altered-genomic-dna-animals
EPA:	https://www.epa.gov/pesticides/biopesticides
CVM Contact:	AskCVM@fda.hhs.gov

I am developing a cell product for use in animals…

…who will regulate the product?

USDA Center for Veterinary Biologics (CVB)

Products regulated under the authority of the Virus-Serum-Toxin Act that meet the definition of animal biological products

FDA CVM

Cell- and tissue-based products regulated under the authority of the FD&C Act that meet the definition of a drug

Document	Link
GFI #218:	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-218-cell-based-products-animal-use
MOU 225-05-7000	https://www.fda.gov/about-fda/domestic-mous/mou-225-05-7000
CVM Contact:	AskCVM@fda.hhs.gov

Additional Resources

- What does FDA regulate? https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate
- Guidance & Regulations: https://www.fda.gov/animal-veterinary/guidance-regulations
- Biotechnology Products at CVM: Animals and Animal Food: https://www.fda.gov/animal-veterinary/development-approval-process/biotechnology-products-cvm-animals-and-animal-food
- The Unified Website for Biotechnology Regulation: https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/

Questions?

For general questions about the review process for IGAs and ACTPs, contact the ONADE Project Management team at CVM_PM_Biotech@fda.hhs.gov

For specific questions about eSubmitter, contact the eSubmitter help desk at cvmesubmitter@fda.hhs.gov

For all other general animal product-related inquiries, contact AskCVM@fda.hhs.gov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