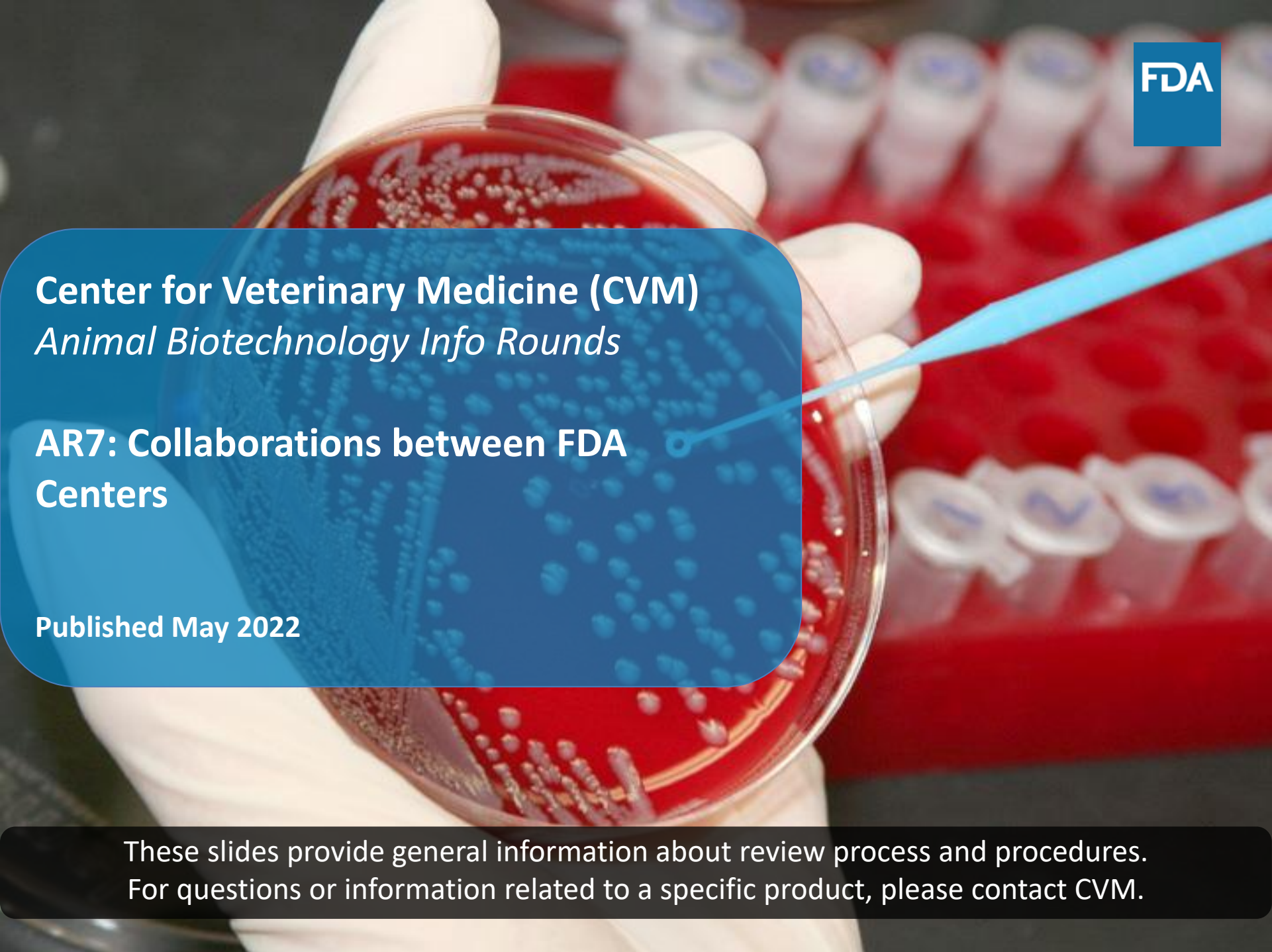

Center for Veterinary Medicine (CVM)

Animal Biotechnology Info Rounds

AR7: Collaborations between FDA Centers

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.

Overview

CVM regulates animal biotechnology products, including intentional genomic alterations (IGAs) in animals and animal cells, tissues, and cell- and tissue-based products (ACTPs). Animal biotechnology products can be used to produce biomedical products (e.g., cells, tissues, organs, biologics) for human use. The applicable FDA Center regulates the biomedical product for human use.

This document provides information on the collaboration of multiple FDA Centers for the review of biotechnology products for cross-center approvals, including:

- Which FDA Centers regulate which biotechnology products, and
- Tips for working with multiple FDA Centers
  - Sharing data between FDA Centers, and
  - Electronic submissions to different FDA Centers.

* Refer to Slide 10 for a list of abbreviations noted throughout the document

FDA Centers that Regulate Biotechnology Products

The Center for Veterinary Medicine (CVM) regulates animal biotechnology products, including IGAs in animals and ACTPs, to ensure effectiveness and safety to the animal.

https://www.fda.gov/about-fda/fda-organization/center-veterinary-medicine

The Center for Biologics Evaluation and Research (CBER) regulates human biological products. Ex: if an animal biotechnology product produces a protein, cell, tissue, or organ for human use, then the animal-derived product would be regulated by CBER to ensure that it is safe and effective in humans.

https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber

The Center for Drug Evaluation and Research (CDER) regulates human biological therapeutics and generic drugs. Ex: if an animal biotechnology product produces a small molecule drug for human use, then the animal-derived drug would be regulated by CDER to ensure that it is safe and effective in humans.

https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder

FDA Centers that Regulate Biotechnology Products, cont'd

The Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting public health by assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. Ex: if an animal biotechnology product produces tissues that are used as a component in a human medical device, then the device would be regulated by CDRH to ensure that it is safe and effective in humans.

https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health

The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. Ex: if edible products derived from animal biotechnology are used as a human food additive, then CFSAN will regulate that food additive.

https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan

Collaboration Between FDA Centers

FDA Centers collaborate and communicate with each other on product development in cases where both an animal and human approval are needed.

For example, when an IGA in an animal is intended to produce a biopharmaceutical for use in humans, there are two regulated articles that require two separate approvals or clearances:

1. The IGA in the animal is subject to CVM's new animal drug application (NADA) approval, and
2. The human biopharmaceutical is subject to approval by the other FDA Center. Examples of applications for approval or clearance from the human centers include the: biologics license application (BLA), new drug application (NDA), 510(k) submission, and premarket approval (PMA) application.

Collaboration Between FDA Centers, cont'd

In these cases, collaboration between the Centers is critical for both the animal and human product approvals. If a product is regulated by multiple Centers, then communications between Centers occur early during the drug development process.

For example, communications may occur during:

- CVM's pre-investigational development (PID) meetings,
- CDER's Critical Path Innovation Meetings (CPIM), or
- CBER's INitial Targeted Engagement for Regulatory Advice on CBER producTs (INTERACT) meetings.

Collaboration Between FDA Centers, cont'd

CVM will coordinate with applicable Center subject matter experts regarding the product development process.

- No action is needed by the developer to initiate the communication between Centers.
- Centers will utilize the Intercenter Collaboration Procedures for an efficient and non-redundant review of products.
- Data may be shared between Centers to facilitate reviews and communications with the sponsor.

Each Center will make its own decision regarding the product over which it has regulatory authority and communicate those decisions to the other Center.

For information on jurisdiction, see AR2: Product Inquiries
https://www.fda.gov/media/152903/download

Resources

- PID meetings: PID is explained as part of the Veterinary Innovation Program (VIP)
  - https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/vip-veterinary-innovation-program
  - AR4 Veterinary Innovation Program (https://www.fda.gov/media/152905/download)
- INTERACT meetings
  - https://www.fda.gov/vaccines-blood-biologics/industry-biologics/interact-meetings-initial-targeted-engagement-regulatory-advice-cber-products
- SMG 4102: Intercenter Coordination of Regulatory Activities for Genetically Engineered Animals and Their Expression Products
  - https://www.fda.gov/media/92780/download
- CPIM
  - https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/critical-path-innovation-meetings-cpim

Sharing Data Between FDA Centers

In some cases, data formally submitted to one Center may be applicable to the development of the product in another Center.

Since each Center has a different data repository, it can be difficult for Centers to share information; therefore, a developer may be asked to submit applicable data to multiple Centers for review.

Information that does not need to be captured formally in the file can be submitted to one Center that will share with the other Center.

- For example, an INTERACT meeting with CBER: meeting materials are submitted to CBER; CBER will share with CVM for review before the meeting.

Electronic Submissions to FDA Centers

Items to note if you are sending submissions electronically:

- Electronic Submission Gateway (ESG) and Electronic Submission System (ESS):
  - For all electronic submissions to any FDA Center, submitters need an ESG account (a.k.a. FDA gateway or WebTrader account).
  - For CVM, submitters also need an ESS account (a.k.a. CVM gateway).

    ESG: https://www.fda.gov/industry/electronic-submissions-gateway

    ESS: https://www.fda.gov/media/120377/download

- eSubmitter: CVM has its own eSubmitter tool for creating submissions.

  CVM eSubmitter: https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-programs

  FDA eSubmitter: https://www.fda.gov/industry/fda-esubmitter/esubmitter-download-and-installation

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

Abbreviations

- ACTPs - Animal cells, tissues, and Cell- and Tissue-based Products
- BLA – Biologics Licensing Applications
- CBER - Center for Biologics Evaluation and Research
- CDER - Center for Drug Evaluation and Research
- CDRH - Center for Devices and Radiological Health
- CFSAN - Center for Food Safety and Applied Nutrition
- CPIM - Critical Path Innovation Meetings
- CVM - Center for Veterinary Medicine
- ESG – Electronic Submission Gateway
- ESS – Electronic Submission System
- IGAs - Intentional Genomic Alterations
- INAD – Investigational New Animal Drug
- INTERACT - **IN**itial **T**argeted **E**ngagement for **R**egulatory **A**dvice on **C**BER produc**T**s
- NADA – New Animal Drug Application
- NDA – New Drug Application
- PID – Pre-Investigational Development
- SMG – Staff Manual Guide
- VIP – Veterinary Innovation Program


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