Center for Veterinary Medicine (CVM)

Animal Biotechnology Info Rounds

AR4: Veterinary Innovation Program (VIP)

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

Overview

This document provides sponsors of intentional genomic alterations (IGAs) in animals and animal cells, tissues, and cell- and tissue-based products (ACTPs) with a brief overview of the **Veterinary Innovation Program (VIP)** and its associated benefits.

The following questions will be covered in these slides.

a. What is the VIP (including its purpose and objective)?

b. What products qualify for the VIP?

c. How do sponsors benefit from participating in the VIP?

d. How do sponsors request participation in the VIP for their product?

e. What are the next steps after submitting a request?

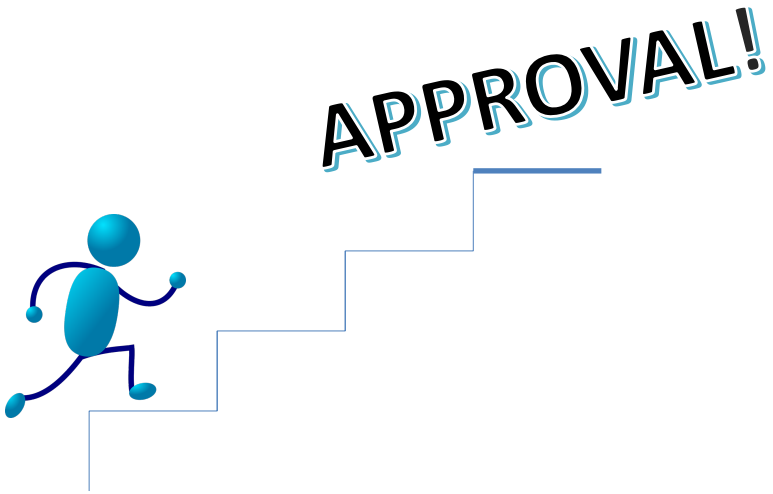
VIP Overview

- The VIP is a program within CVM that was launched in 2018
- The VIP was designed to support a predictable and efficient pathway to approval of certain **IGAs** in animals and certain **ACTPs**.

VIP Objective

The objective of the VIP is to facilitate advancements in the development of innovative products by:

- Providing more flexibility throughout the regulatory process,
- Encouraging research and development, and
- Supporting an efficient and predictable pathway to approval



VIP Eligibility and Benefits

The VIP is for certain sponsors of ACTPs and IGAs in animals that are **seeking approval** and that provide a benefit to at least one of the following:

- Human or animal health,
- Enhanced food production, or
- Animal well-being.

For information on how to participate in the VIP, contact the Project Manager Mailbox (CVM_PM_Biotech@fda.hhs.gov).

VIP benefits fall into three categories, which will be expanded upon in the next few slides:

- Intensive interaction,
- Hands-on assistance, and
- Review process benefits.

VIP Benefits

Intensive Interaction

Sponsors participating in the VIP will benefit from an increased number of reviewer-led sponsor meetings and early communication that will focus on facilitating product development and addressing sponsor questions. These interactions include the following:

- **Pre-investigational development (PID) meeting,**
- **Pre-review feedback, and**
- **Post-review feedback meeting.**

Additional information on meetings conducted under the VIP can be found in the following document: "AR2: Product Inquiries" (https://www.fda.gov/media/152903/download).

For more information, send an email to the PM mailbox (CVM_PM_Biotech@fda.hhs.gov).

VIP Benefits

Intensive Interaction

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VIP participants benefit from collaboration with CVM experts.

- ***Review Team:*** CVM's team of experts is assembled when the sponsor is ready to have recurring communications regarding product development. This team will include a lead reviewer (the scientific point of contact), project managers, and subject matter experts (e.g., biologists, animal scientists, veterinarians, chemists, toxicologists, statisticians, and environmental scientists) that will review the product.
- ***Senior Management Involvement:*** Senior CVM leadership will be informed of regulatory challenges that impact product development and approval and can therefore advise the review team in addressing such challenges and ensure the availability of appropriate resources.

VIP Benefits

Hands-On Assistance

The VIP allows for a collaborative approach between the sponsor and CVM experts.

- ***Identification and Assay Methods:*** The review team may discuss potential methodologies for assay development and offer technical advice to sponsors submitting protocols for method validation prior to a technical section submission. The review team may leverage expertise from regulatory reviewers in the Office of New Animal Drug Evaluation (ONADE) and research scientists in the Office of Research (OR).
- ***Post-Approval Obligations:*** Experts from the Office of Surveillance and Compliance (OSC) will help the sponsor prepare for, and meet, their post-approval requirements. This includes ensuring that the product is establishment registered and drug listed prior to approval and assisting the sponsor with post-approval reporting and changes.

VIP Benefits

Review Process Benefits

Stopping the Review Clock: During review of major technical section submissions, CVM may identify key elements that are either missing or unacceptable. In certain cases, CVM may stop the review clock[1] for these submissions and provide feedback to the sponsor without closing out the submission or removing it from the queue. This benefit:

- allots time for the sponsor to address CVM's feedback and submit an amendment while the clock is stopped, and
- decreases the number of review cycles and shortens the time that it takes to complete each technical section in support of an approval.

See the next slide for an example of stopping the review clock in action.

[1] The review clock is the statutory timeframe designated for each submission type under the Animal Drug User Fee Act (ADUFA). Under the 2018 ADUFA authorization, each technical section has a 180-day review clock. For more information about ADUFA, see https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.

VIP Benefits

Review Process Benefits: Example of Stopping the Review Clock

Example: A sponsor submits a Claim Validation technical section (TS), which starts a 180-day review clock. The review team notes that the sponsor has not provided a method validation needed to support the data. The missing information is requested in either of the following two scenarios:

Sponsor participating in VIP:	Sponsor not participating in VIP:
CVM stops the clock and issues "Stop the Clock" letter within 180-day timeframe (e.g., the clock stops on day 120)	Submission is incomplete; CVM issues "TS Incomplete" letter by day 180
Sponsor submits the requested information; review clock restarts (in this case, 60 days remain on the review clock). CVM finds all information acceptable	Sponsor submits a reactivated TS including the information requested in the incomplete letter; new 180-day review clock begins. CVM finds all information acceptable
"TS Complete" letter is sent by the new due date.	"TS Complete" letter is sent by day 180.
Total review time is 180 days	**Total review time is 360 days**

VIP Benefits

Review Process Benefits

Alternative Data Options: In support of an approval, CVM may accept alternative strategies for generating data or the submission of different types of data. For example, CVM may accept:

- Data from a limited number of generations or limited number of animals
- Data intended to support multiple cell lines
- Data generated through collaboration across institutions

CVM may assist in the development of alternative strategies for meeting the data requirements for approval (e.g., alternative approaches to statistical analyses or risk-based plans for evaluation of safety). This, in turn, should reduce the potential for regulatory and scientific barriers that may impact the efficiency of the approval process.

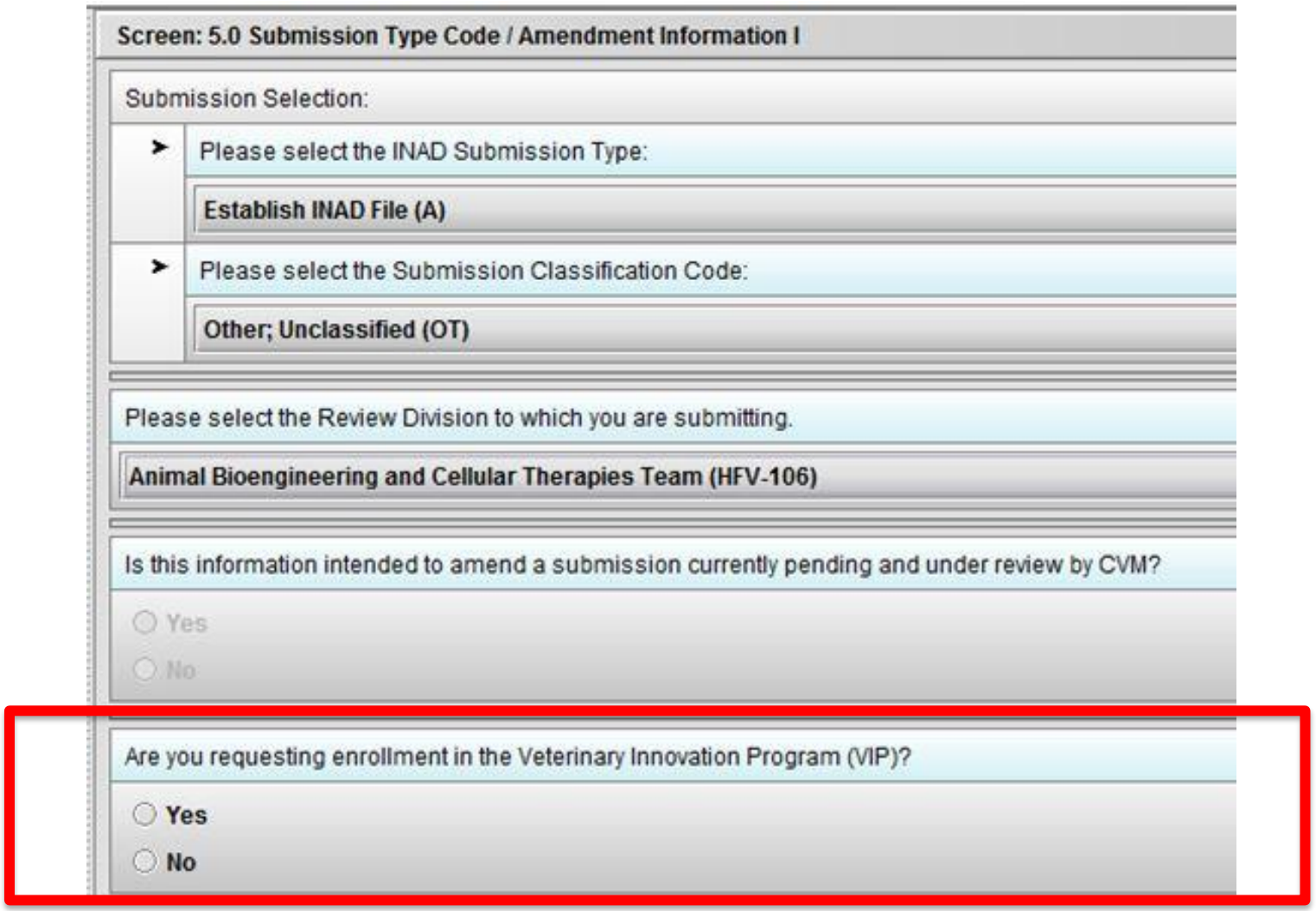
Requesting Participation in the VIP

Requests for participation in the VIP may be included in the cover letter to a request for opening a new file (i.e., an **"A" submission**). If this request is submitted through CVM eSubmitter, then the template prompts the sponsor to choose whether or not to enroll the product in the VIP.

For products under existing Veterinary Master Files (VMFs) or INAD files, the sponsor may request to participate in the VIP under a **"G" submission**.

See the next slide for a snapshot of the CVM eSubmitter template for a request to open an Investigational New Animal Drug (INAD) file.

Requesting Participation in the VIP



VIP Qualification and CVM Response

CVM will respond to the sponsor's VIP request by email within 30 days to inform them of their VIP status.

If the sponsor qualifies for the VIP, then the VIP toolkit (see next slide) will be included as an enclosure in their acknowledgement letter. This letter is sent within the ADUFA review timeframe based on the submission type.

Additional information regarding the VIP can be found on the FDA VIP webpage: https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/vip-veterinary-innovation-program

VIP Toolkit

Qualifying sponsors will receive the **VIP Toolkit** with their decision letter.

- The VIP toolkit is a curated list of helpful resources that is based on the intended use of the ACTP or IGA in animals. These resources will help sponsors generate quality submissions.
- Examples of resources in the toolkit include:
  - Weblinks to:
    - Guidances for Industry (GFIs) and Policies and Procedures (P&Ps),
    - Webpages and videos that help with eSubmitter,
    - Useful resources specific to ACTPs or IGAs in animals,
  - Information on the VIP benefits, and
  - Contact information.

See the next slide for a snapshot of the first page of the VIP toolkit for a sponsor of an IGA in an animal.

THE VETERINARY INNOVATION PROGRAM (VIP) TOOLKIT FOR SPONSORS

Unless otherwise stated, many of the resources in this toolkit are intended for the development of small-molecule pharmaceuticals. While these resources are not specific to intentional genomic alterations (IGAs) in animals, the general principles are applicable. We encourage you to meet with the Center for Veterinary Medicine (CVM) to discuss the approval process for your product.

GENERAL INFORMATION FOR NAVIGATING THE DRUG APPROVAL PROCESS

General Guidance for Industry (GFI) Documents

Getting Started

CVM GFI #170 – Animal Drug User Fees and Fee Waiver Reductions
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-170-animal-drug-user-fees-and-fee-waivers-and-reductions

CVM GFI #173 – Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-173-animal-drug-sponsor-fees-under-animal-drug-user-fee-act-adufa

CVM GFI #173 - Appendix for the Animal Drug Sponsor Fees Under the ADUFA
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-173-appendix-animal-drug-sponsor-fees-under-adufa

CVM GFI #132 – Administrative Applications and the Phased Review Process
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-132-administrative-applications-and-phased-review-process

Evaluating Safety and Effectiveness

CVM GFI #85 (VICH GL9) – Good Clinical Practice

Questions?

For general questions about the approval 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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