Center for Veterinary Medicine (CVM)
Animal Biotechnology Info Rounds

AR5: Opening a File

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

FDA

Overview

FDA

This document provides an overview of the information to support opening an investigational new animal drug (INAD) file or a veterinary master file (VMF). Both document types are utilized by developers of intentional genomic alterations (IGAs) in animals and animal cells, tissues, and cell- and tissue-based products (ACTPs) to submit information to CVM during the development of animal biotechnology products.

Note: This document refers to the Animal Drug User Fee Act (ADUFA). For more information about ADUFA, see FDA's ADUFA website: https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa

Investigational New Animal Drug Files

An INAD file is a confidential repository of information used to support an approval and subject to ADUFA fees. An INAD file is opened when a developer is:

- ready to generate data supporting the approval of a New Animal Drug Application (NADA),
- ready for binding discussions with CVM, or
- submitting data for review in support of technical sections

The use of an INAD file allows for:

- conduct of studies to support an approval,
- shipment of investigational animals or products (including ACTPs and IGAs in animals) for use in studies,
- meetings that result in binding agreements with CVM,
- review of data supporting an approval, and
- requests for Investigational Food Use Authorizations (IFUAs)

Veterinary Master Files

A VMF is a confidential repository of information that is not subject to ADUFA fees. A VMF may be more appropriate than an INAD file based on the type of information that you plan to submit.

For more information regarding VMFs, please see:
https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-master-files

Determining the Appropriate File Type

Contact CVM to find out whether a VMF or INAD file is the appropriate file for your product.

- "Ask CVM" mailbox at AskCVM@fda.hhs.gov

- Project Manager mailbox at CVM_PM_Biotech@fda.hhs.gov

Opening a File

In general, we ask that a request to open a file include:

- Administrative information:
  - A statement requesting to open a file,
  - Contact information for the person responsible for activities associated with the file, and
  - A statement that investigational animals will not be introduced into the human or animal food supply.

- Product-specific information:
  - Overview of project objectives,
  - Description of the animal species and class, if applicable,
  - Description of the product under development, and
  - Claim and conditions of use for the product under development.

See the next slides for IGA- and ACTP-specific information.

Product-Specific Information – IGAs in animals

For IGAs in animals, we ask that the request to open a file also include a description of:

- All animal facilities involved in the development of IGAs in animals (e.g., facility name, address and owner/operator). Production facilities (e.g., farmers) are not included,

- Physical containment (e.g., perimeter fence, barns, pens,) and procedural containment (e.g., security measures, employee training, emergency plan) at all facilities. Diagrams and pictures are helpful here,

- Animal identification methods (e.g., permanent tattoos, ear notching, tags),

- Animal husbandry, including veterinary care,

- Animal disposal (e.g., incineration, composting) and animal waste (e.g., urine, feces) disposal procedures, and

- Animal transportation and shipping procedures.

Product-Specific Information – ACTPs

For ACTPs, we ask that the request to open a file also include:

- A description of the dose, route of administration, and frequency of administration,

- A description of the formulation including information about components in the product in addition to the cell- or tissue-based components (e.g., cryoprotectant, media),

- Information about characterization, product manipulations, and mechanism of action (if known),

- Summary of the results of any pilot studies already completed, and

- A list of ongoing or upcoming studies.

Electronic Submissions

Information may be submitted using CVM's electronic submission portal, eSubmitter. Submissions via eSubmitter are:

- Confidential,
- Intended to ensure reliable transmission of data and information between developers and CVM, and
- Efficient.

Information on getting started with eSubmitter and setting up the account:

https://www.fda.gov/industry/fda-esubmitter/getting-started-esubmitter

General information on using CVM's eSubmitter:

https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center

Using eSubmitter to Open a File

CVM has made available videos with step-by-step instructions on how to use the CVM eSubmitter templates. For videos for the Division of Animal Bioengineering and Cellular Therapies, including videos about opening INAD and VMF files for IGAs in animals and ACTPs, follow the link below:

https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center#webinars

(Note: CVM made the following recordings on 8/22/2018, and since then, the center may have updated some of the eSubmitter templates.)

As part of this series, we have provided information on selecting the correct document and submission types in AR3: CVM eSubmitter (https://www.fda.gov/media/152904/download).

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