

**Center for Veterinary Medicine (CVM)**  
*Animal Biotechnology Info Rounds*

**AR1: General Resources**

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.



# Getting Started

This document provides developers of intentional genomic alterations (IGAs) in animals and animal cells, tissues, and cell- and tissue-based products (ACTPs) with online resources that provide general information about FDA and CVM as well as specific information on how to navigate the regulatory process.

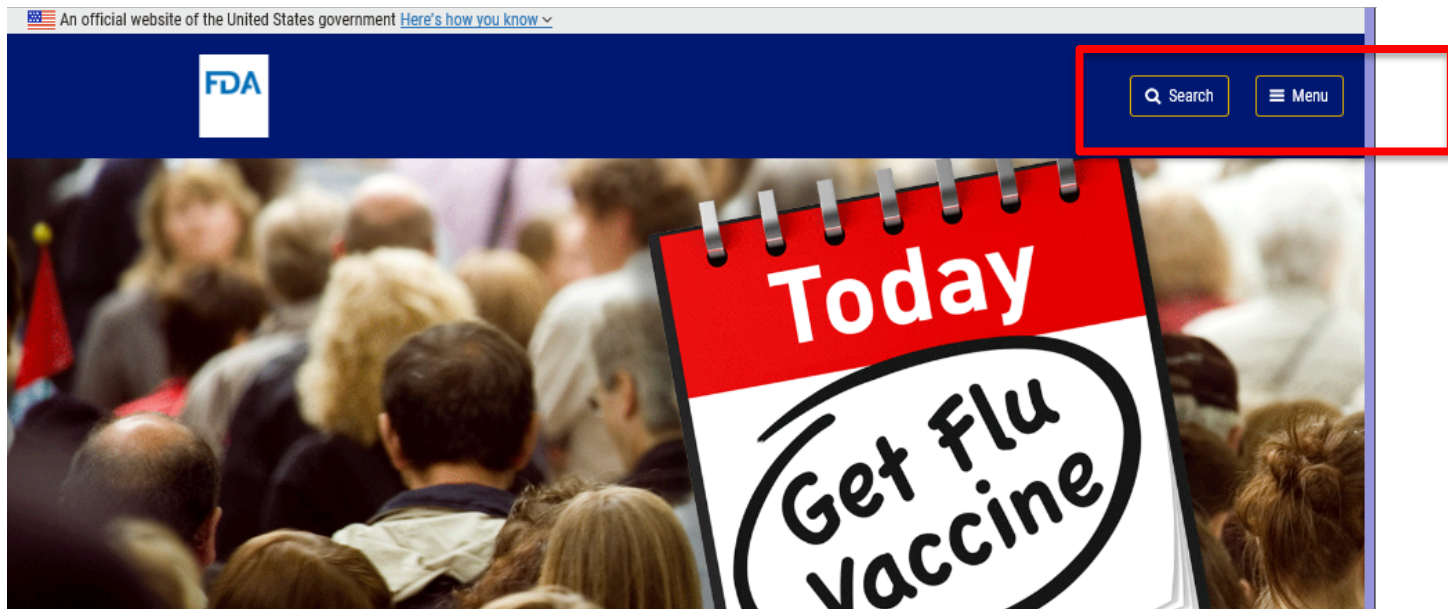
Many of the resources described here are not specific to biotechnology products; rather, these resources explain how to navigate and search for specific information on FDA's website.

The next page demonstrates how to search on FDA's website.

# FDA Homepage: <https://www.fda.gov/>

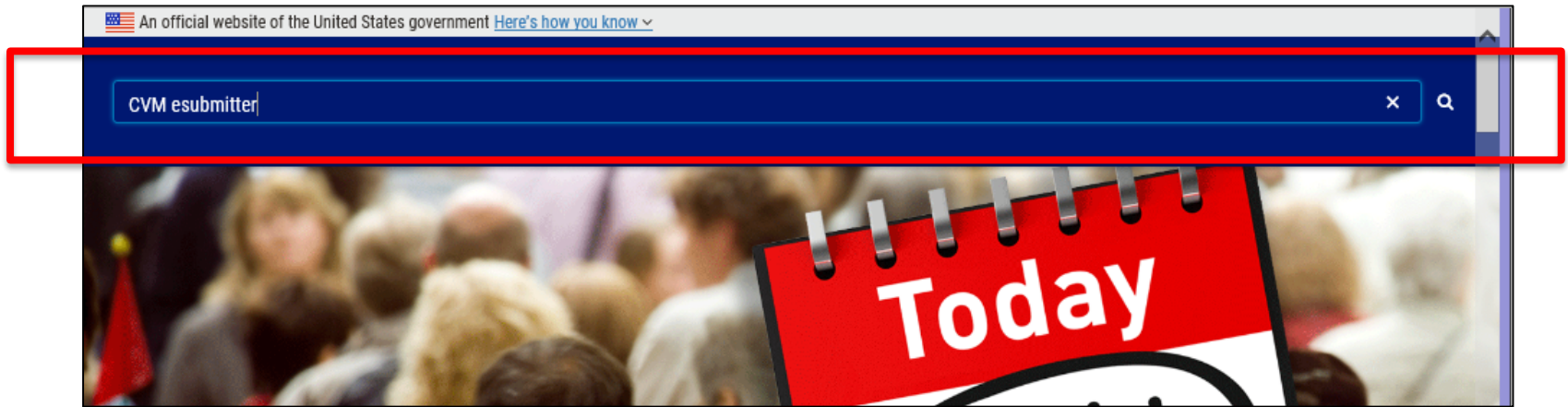


On the FDA homepage, the search function is in the top right corner of the page. Click on the search button...



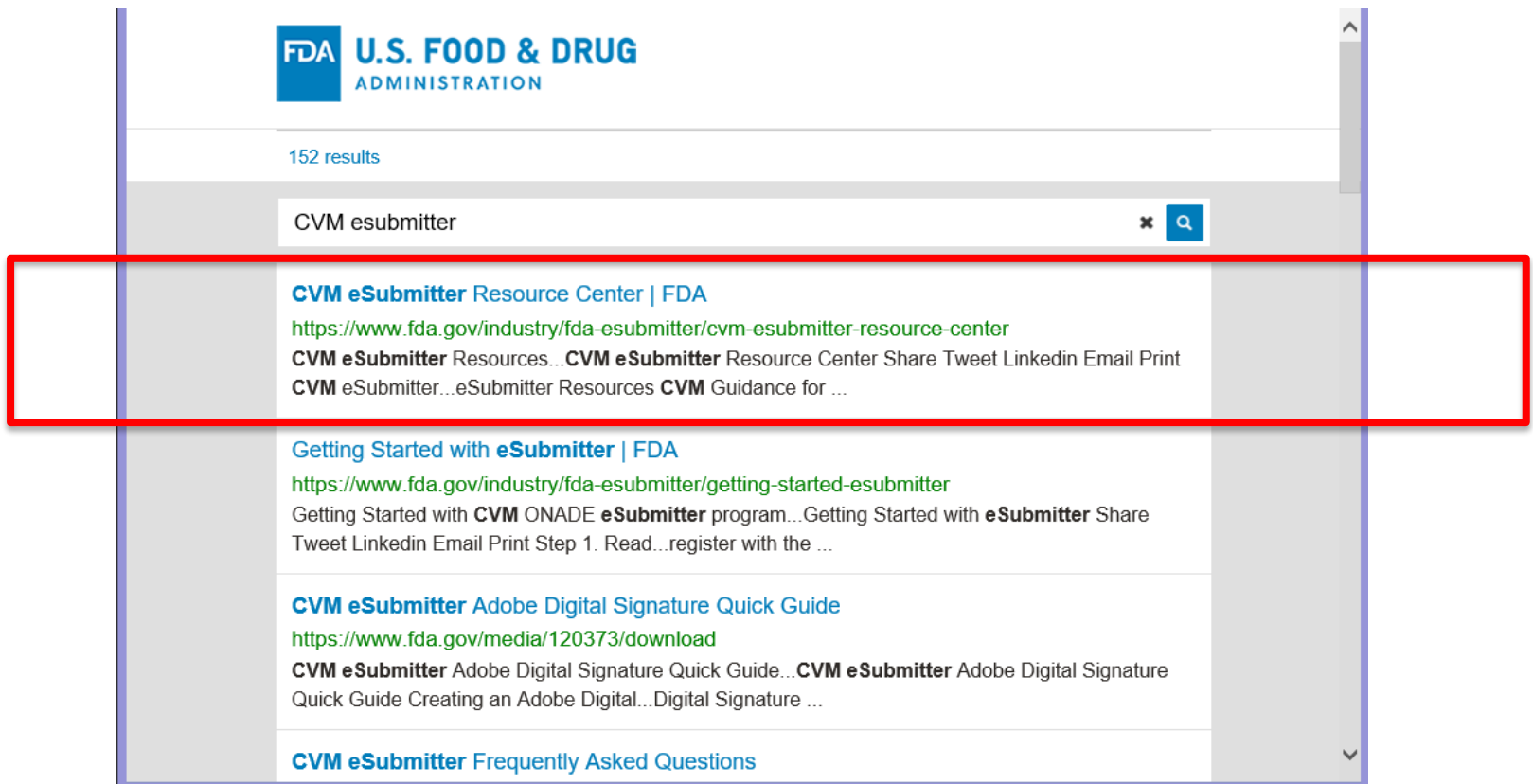
# FDA Homepage: <https://www.fda.gov/>, cont'd

...to activate a space to enter a search query. In this case, a user typed “CVM eSubmitter” in the search bar to search for FDA web pages that are about eSubmitter.



# Search Results

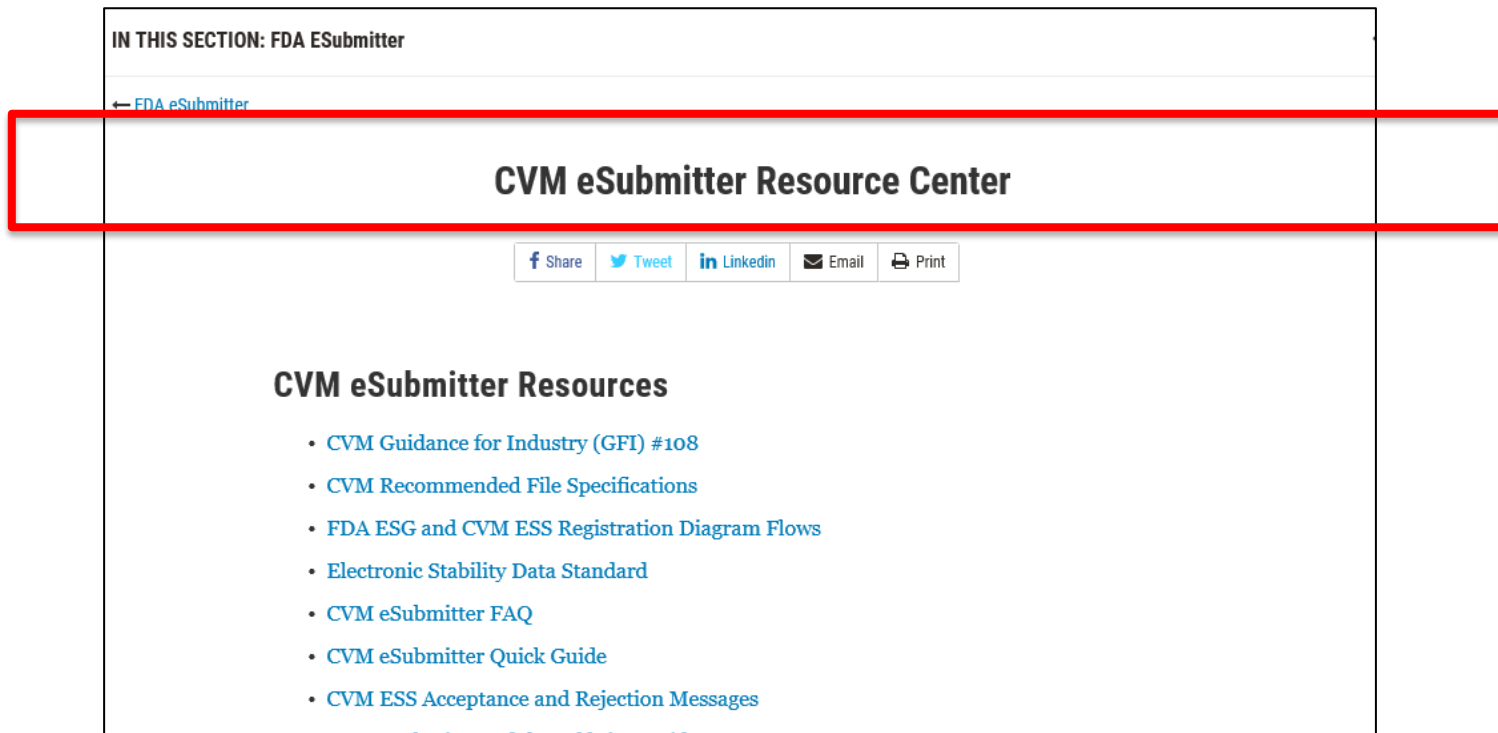
The search results, as shown here, provide links to all related pages. The most relevant topic appears at the top...



The screenshot shows the FDA website search interface. At the top left is the FDA U.S. Food & Drug Administration logo. Below it, the text "152 results" is displayed. A search bar contains the text "CVM esubmitter" with a search icon to its right. Below the search bar, a list of search results is shown. The first result is highlighted with a red rectangular box. This result is titled "CVM eSubmitter Resource Center | FDA" and includes the URL "https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-resource-center". Below the URL, there is a snippet of text: "CVM eSubmitter Resources...CVM eSubmitter Resource Center Share Tweet Linkedin Email Print CVM eSubmitter...eSubmitter Resources CVM Guidance for ...". The second result is titled "Getting Started with eSubmitter | FDA" and includes the URL "https://www.fda.gov/industry/fda-esubmitter/getting-started-esubmitter". The third result is titled "CVM eSubmitter Adobe Digital Signature Quick Guide" and includes the URL "https://www.fda.gov/media/120373/download". The fourth result is titled "CVM eSubmitter Frequently Asked Questions".

# Resource Center

...which leads to a dashboard that provides resources about CVM eSubmitter. In this example, the resources include a Guidance for Industry (GFI), a Frequently Asked Questions (FAQ) page, and other resources such as a quick guide and submission specifications.



The screenshot shows a web page titled "CVM eSubmitter Resource Center". At the top, it says "IN THIS SECTION: FDA ESubmitter" and has a breadcrumb link "← FDA eSubmitter". Below the title is a row of social sharing icons: Facebook Share, Twitter Tweet, LinkedIn, Email, and Print. The main content area is titled "CVM eSubmitter Resources" and contains a list of links:

- [CVM Guidance for Industry \(GFI\) #108](#)
- [CVM Recommended File Specifications](#)
- [FDA ESG and CVM ESS Registration Diagram Flows](#)
- [Electronic Stability Data Standard](#)
- [CVM eSubmitter FAQ](#)
- [CVM eSubmitter Quick Guide](#)
- [CVM ESS Acceptance and Rejection Messages](#)



# FDA resource: <https://www.fda.gov/industry/fda-basics-industry>



One notable FDA resource is the FDA Basics for Industry webpage. On the left side, there is a menu that lists the topic areas, which helps new developers navigate the regulatory process.

← Home / For Industry / FDA Basics for Industry

## FDA Basics for Industry

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

- FDA Basics for Industry
  - Guidances
  - Registration and Listing
  - Regulatory Process
  - Product Application and Petition Review Process
  - Stay Informed With FDA Program Areas
  - Search Databases
  - Popular Content
  - Industry Frequently Asked Questions

### What should I expect during an inspection?



FDA may conduct an inspection of your operation for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem.

[More](#)

I want to manufacture an FDA-regulated product. Where do I start?

### ResourcesForYou

- [Transparency Initiative](#)
- [FDA Basics](#)
- [Transparency Blog](#)

Content current as of: 12/10/2020



## Available Resources

The next several slides describe resources that are specific to animal biotechnology products: IGAs in animals and ACTPs.

These resources focus on general information about regulation of these products. For questions about the regulatory process or submission requirements, contact CVM ([AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov)).



# US Government and FDA Resources



Website	Summary	URL
The Unified Website for Biotechnology Regulation	Describes the role of FDA, USDA, and EPA in biotechnology product regulation	<a href="https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/">https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/</a>
Biotechnology Products at CVM: Animals and Animal Food	Describes CVM's regulatory approach to intentional genomic alterations in animals and animal cells, tissues, and cell- and tissue-based products, including links to relevant information.	<a href="https://www.fda.gov/animal-veterinary/development-approval-process/biotechnology-products-cvm-animals-and-animal-food">https://www.fda.gov/animal-veterinary/development-approval-process/biotechnology-products-cvm-animals-and-animal-food</a>
Veterinary Innovation Program (VIP)	Describes CVM's program to facilitate the approval process for IGAs in animals and ACTPs.	<a href="https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/vip-veterinary-innovation-program">https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/vip-veterinary-innovation-program</a>

# Dashboard for IGAs in Animals

This dashboard provides background and resources on the regulatory process for IGAs in animals.

An official website of the United States government [Here's how you know](#)

**FDA U.S. FOOD & DRUG ADMINISTRATION** Search Menu

[Home](#) / [Animal & Veterinary](#) / [Development & Approval Process](#) / [Biotechnology Products at CVM: Animals and Animal Food](#) / [Intentional Genomic Alterations \(IGAs\) in Animals](#)

## Intentional Genomic Alterations (IGAs) in Animals

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**Intentional Genomic Alterations (IGAs) in Animals**

Intentional Genomic Alterations (IGAs) in Animals: Low Risk IGAs

FDA's Response to Public Comments on Draft Guidance for Industry #187, Released 9/18/2008

Q&A on FDA Regulation of Intentional Genomic

IGAs in animals are changes to an animal's genomic DNA produced using modern molecular technologies, which may include random or targeted DNA sequence changes including nucleotide insertions, substitutions, or deletions. The IGA can be introduced into the animal's genome using recombinant DNA, genome editing, or other technologies. IGAs in animals have many different intended uses, including applications in human health (e.g., reduced allergenicity, "biopharm" animals (that produce substances, generally in their milk or eggs, that are used in the production of human therapeutics, animals used to model human disease), in improved animal health, well-being, and husbandry practices (e.g., disease resistance, heat tolerance), and in enhanced production and food quality (e.g., faster growth, feed efficiency, nutritional benefits).

**Guidance for Industry (GFI) #187**

In January 2017, FDA CVM released [draft revised GFI #187 "Regulation of Intentionally Altered Genomic DNA in Animals"](#) for public comment. This draft revised guidance

Content current as of: 04/28/2022

<https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/intentional-genomic-alterations-igas-animals>



# Dashboard for ACTPs

This dashboard provides background and resources on the regulatory process for ACTPs.

An official website of the United States government [Here's how you know](#) -

**FDA U.S. FOOD & DRUG ADMINISTRATION** Search Menu

← Home / Animal & Veterinary / Development & Approval Process / Biotechnology Products at CVM: Animals and Animal Food / Cell and Tissue Products for Animals

## Cell and Tissue Products for Animals

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**Cell and Tissue Products for Animals**

FDA's Role in Veterinary Regenerative Medicine

Animal Cells, Tissues, and Cell- and Tissue-Based Products (ACTPs): Lower Risk ACTPs

Q&A for Developers of Animal Cells, Tissues, and Cell- and Tissue-Based Products (ACTPs)

Q&A for Pet Owners on

### Animal Cells, Tissues, and Cell- and Tissue-Based Products (ACTPs)

ACTPs are 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. Examples include animal stem cells, differentiated cells, and tissues such as blood, platelet-rich plasma, and amnion.

### Guidances for Industry (GFIs)

In June 2015, FDA CVM issued [GFI #218](#), which discusses the approval requirements for ACTPs that meet the legal definition of a “drug” and how the agency intends to regulate them.

In September 2021, FDA CVM issued two draft guidance documents that, if finalized, will help developers and manufacturers of ACTPs understand current good manufacturing

Content current as of: 04/28/2022

<https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/cell-and-tissue-products-animals>



# 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](mailto:CVM_PM_Biotech@fda.hhs.gov)

For specific questions about eSubmitter, contact the eSubmitter help desk at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

For all other general animal product-related inquiries, contact [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov)

