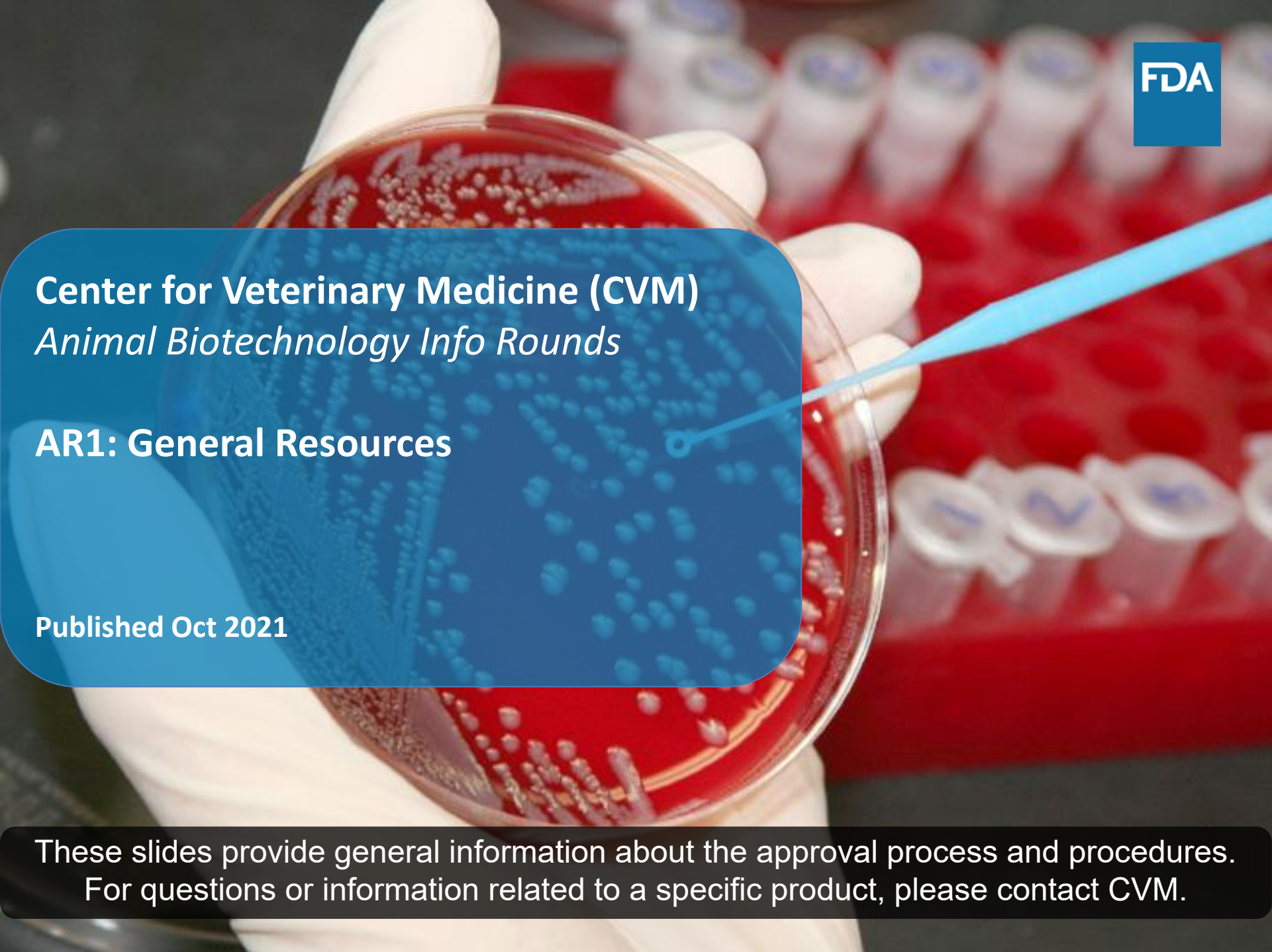


Center for Veterinary Medicine (CVM)

Animal Biotechnology Info Rounds

AR1: General Resources

Published Oct 2021

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

Getting Started

This document provides sponsors 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.

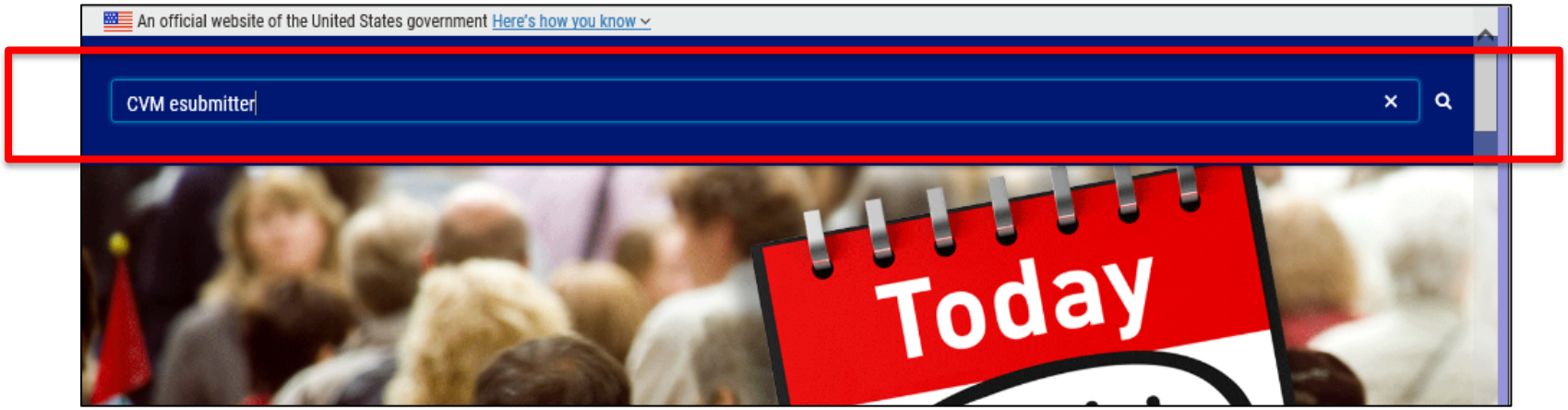
The next page demonstrates how to search on FDA's website.

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…

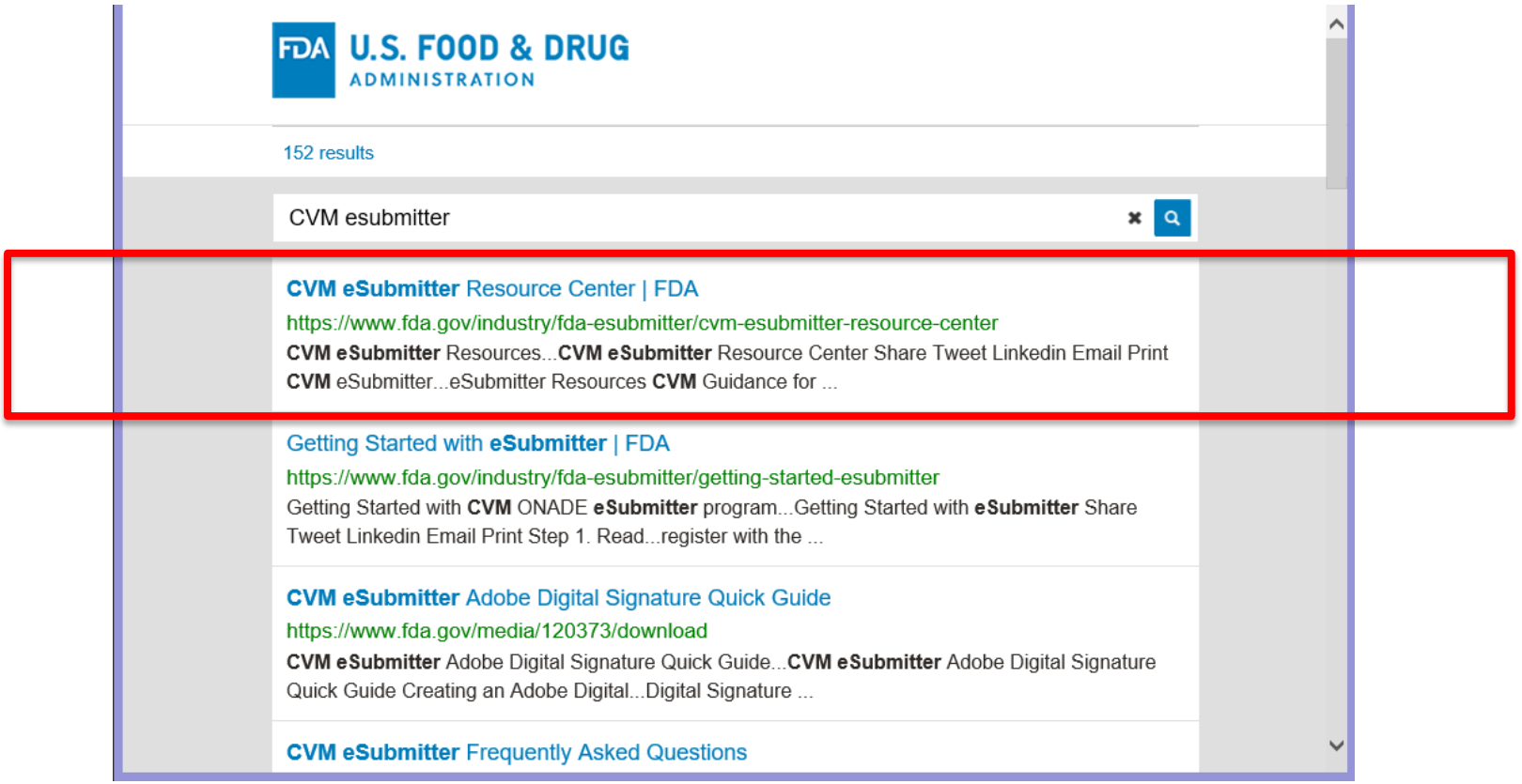
FDA Homepage: https://www.fda.gov/

…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.



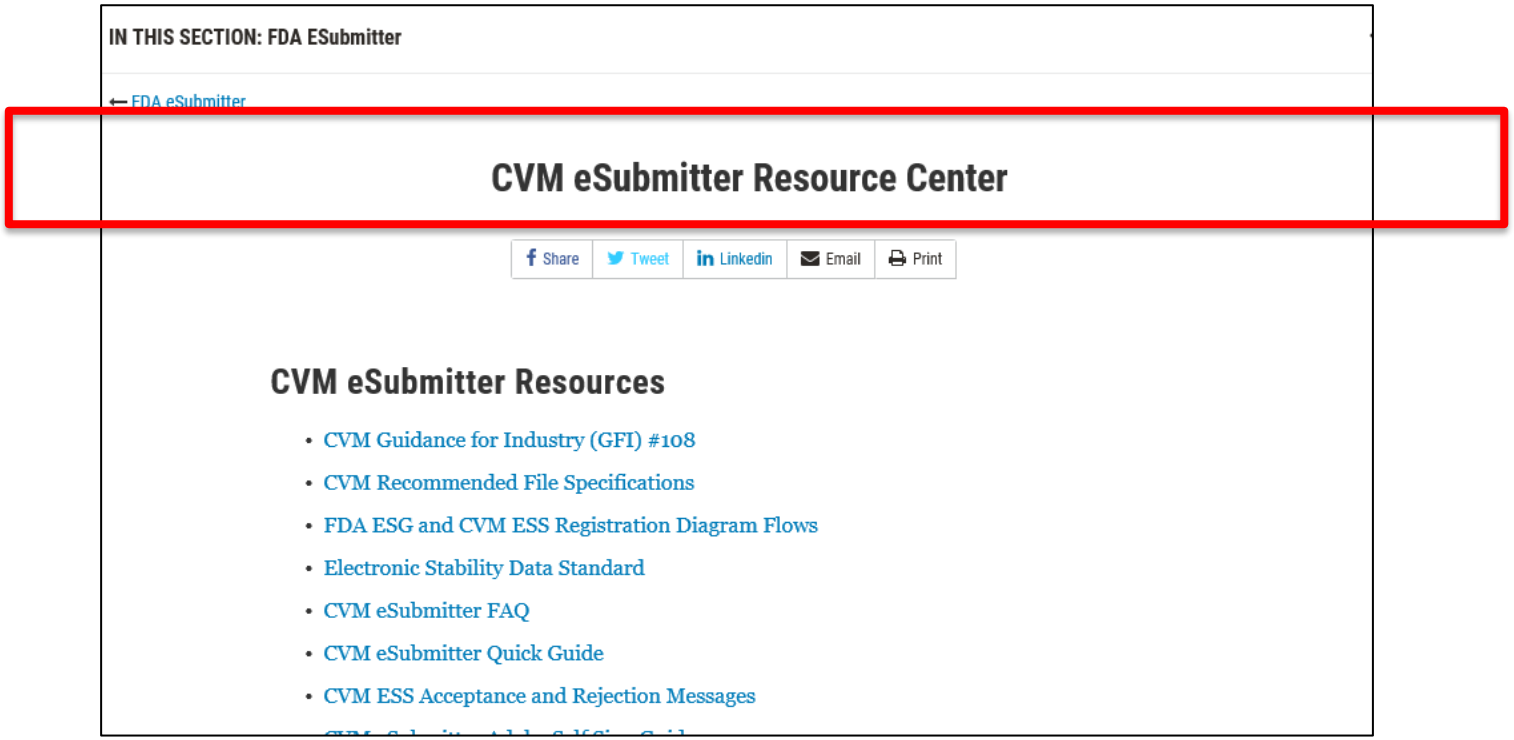
Search Results

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



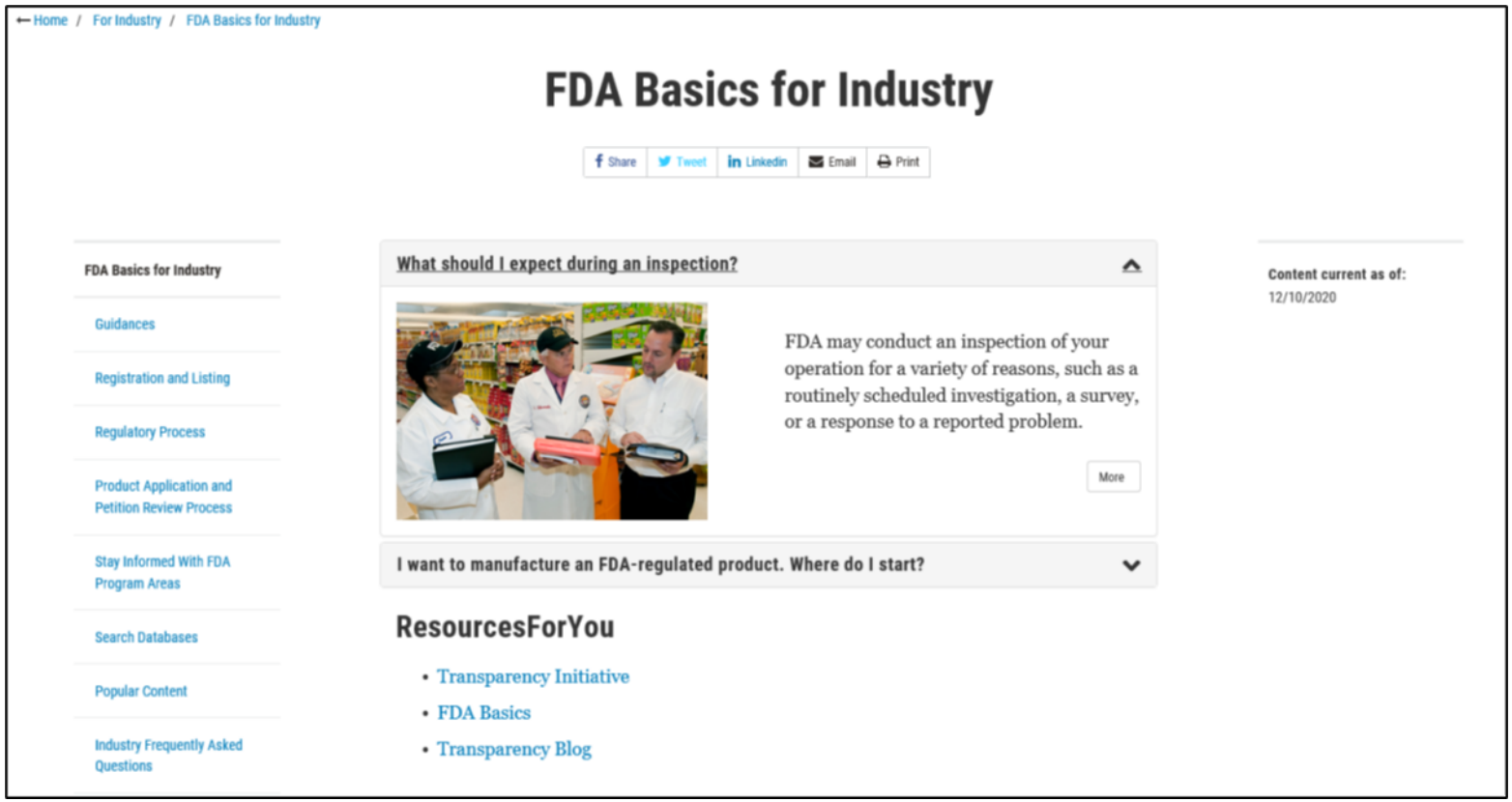
Resource Center

…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.



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 sponsors navigate the regulatory process.



Available Resources

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

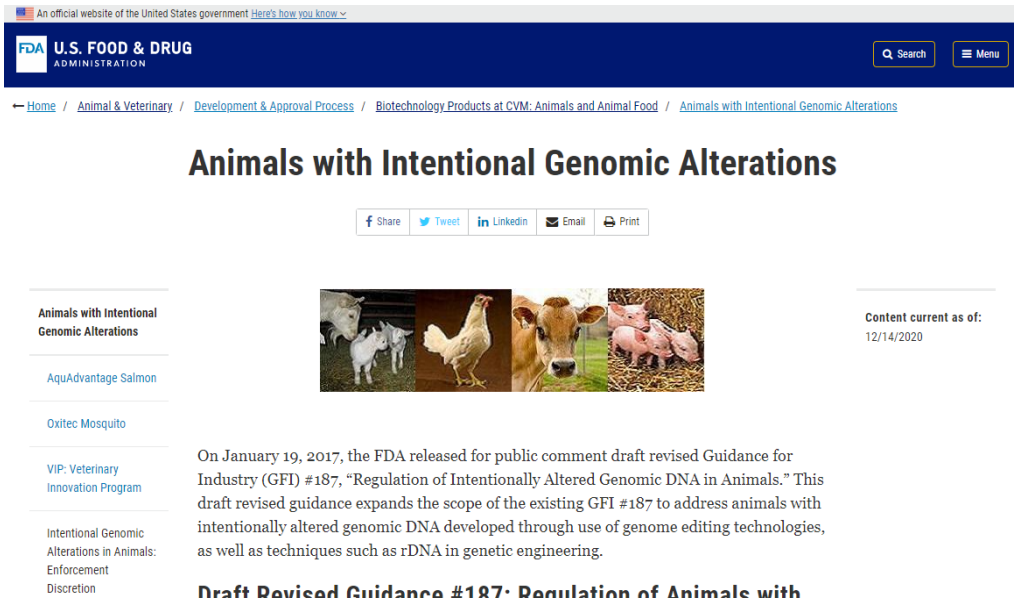
These resources focus on general information about regulation of these products. For questions about the regulatory process or submission requirements, contact CVM (AskCVM@fda.hhs.gov).

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	https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/
Biotechnology Products at CVM: Animals and Animal Food	Describes CVM's regulatory approach to intentional genomic alterations in animals, including links to relevant information.	https://www.fda.gov/animal-veterinary/development-approval-process/biotechnology-products-cvm-animals-and-animal-food
Veterinary Regenerative Medicine & Animal Cell-Based Products	Describes CVM's regulatory approach to cell- and tissue-based products.	https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-regenerative-medicine-animal-cell-based-products
Veterinary Innovation Program (VIP)	Describes CVM's program to facilitate the approval process for IGAs in animals and ACTPs.	https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/vip-veterinary-innovation-program

Dashboard for IGAs in Animals

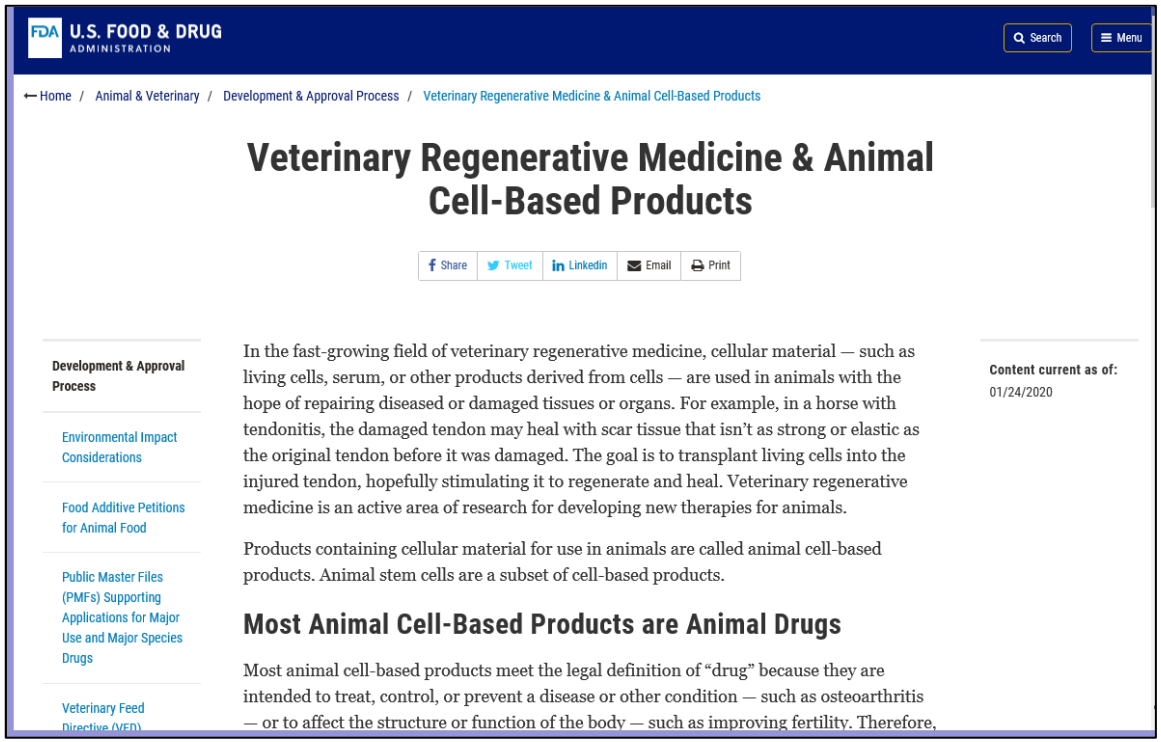
This dashboard provides background and resources on the regulatory process for IGAs in animals.



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

Dashboard for ACTPs

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



https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-regenerative-medicine-animal-cell-based-products

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


FDA
U.S. FOOD & DRUG
ADMINISTRATION