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Licensing a Biologic: Suggestions for New Applicants

Last Modified:

New applicants are encouraged to contact the Center for Veterinary Biologics (CVB) early in the product development process. A licensing reviewer will be assigned to help you through the regulatory process. Initially, the CVB will confirm that the proposed product meets the definition of a veterinary biologic and is subject to regulation by the CVB.

The proposed manufacturing and testing facilities must also meet the standard requirements as outlined in the 9 CFR, Part 108. Manufacturing facilities located in communal buildings, such as University Research Parks or New Business Incubator buildings may not meet the control and quality standards required for the manufacturing of a veterinary biological product. These shared spaces bring with them a host of issues not seen with a traditional manufacturing setting. A reminder to new applicants considering a communal manufacturing site; the entire building would be considered licensed premises and as such the entire building would be subject to inspection by the Center for Veterinary Biologics.

We then recommend that applicants submit a licensing plan, including pivotal study protocols, to the CVB for review and comment prior to initiating work that will be used to support product licensure.

Guidance Documents

A complete listing of the regulations and guidance documents pertinent to veterinary biologics is found on the CVB's Program Regulations and Guidance page. We encourage new applicants to read the following documents in particular:

Veterinary Services Memorandum 800.50

Basic License Requirements and Guidelines for Submission of Materials in Support of Licensure

Veterinary Services Memorandum 800.101

U.S. Veterinary Biological Product Permits for Distribution and Sale (guidance specific to imported products)

Veterinary Services Memorandum 800.73

(PDF, 350.3 KB)

General Requirements for Immunodiagnostic Test Kits for the Detection of Antibody or Antigen (guidance specific to diagnostic test kits)

Veterinary Services Memorandum 800.200

General Licensing Considerations: Study Practices and Documentation

Veterinary Services Memorandum 800.87

Guidelines for Licensing Establishments with Separated Premises

Veterinary Services Memoranda

Other "General Licensing Considerations" found in the "800.2XX" series of the Veterinary Services Memoranda.

Submission Compliance Guide

(PDF, 1.58 MB)

Submitting Complete and Accurate License Applications, Outlines, and Labels (for paper submissions only)

Guidance for New Firms

- Guidance for Reviewers on Portal Access for New Firms (184.85 KB) CVB-WI-5233
- New Firm Informational Packet for Antivenin Products (270.31 KB) CVB-WI-5234
- New Firm Informational Packet for Cancer Products and Immunomodulatory Products that Require Client Owned Animals Efficacy and Safety Studies (309.28 KB) CVB-WI-5235
- New Firm Informational Packet for Diagnostic Test Kits (289.75 KB) CVB-WI-5236
- New Firm Informational Packet for Live and Inactivated Vaccines Including Recombinants (280.34 KB) CVB-WI-5237
- Guidance on the NCAH Portal - access is reserved for those firms and/or products that are close to licensure as determined by the CVB
- NCAH Portal Access Information

Training Opportunity

The Institute for International Cooperation in Animal Biologics (IICAB) works to improve the availability, safety, efficacy and use of veterinary biologics (vaccines and diagnostics) throughout the world. Veterinary biologics are a cost-effective

method to prevent animal disease, to increase the efficiency of food production, and to increase the availability of high quality protein for humans. The Institute was established in 1995 by the USDA Animal and Plant Health Inspection Service and Iowa State University. The **Veterinary Biologics Training Program (VBTP) provides an overview of the USDA regulatory process for assuring the purity, safety, potency and efficacy of veterinary biologics** (vaccines, bacterins, antisera, diagnostic kits and other products of biological origin).

Representatives from the USDA Animal and Plant Health Inspection Service's (APHIS) Center for Veterinary Biologics (CVB) present information on the requirements and processes for licensing/registration and testing of veterinary biological products. The inspection and compliance process for production, release and post-marketing surveillance of veterinary biological products is covered in both lectures and workshops. Professionals working in the veterinary biologics industry, researchers developing biologics, and regulatory personnel are encouraged to attend and learn about current CVB requirements. **This course is a highly regarded overview of the current regulatory guidelines in the U.S.** The Program is organized by the Institute for International Cooperation in Animal Biologics (IICAB) and is co-sponsored by the USDA APHIS CVB and the Iowa State University College of Veterinary Medicine. The Program has been offered annually from 1996-2019. Over 3000 individuals have attended the program, including 876 international attendees from 96 countries.

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