Regulation of phages used in veterinary medicine in the U.S.

IABS Webmeeting

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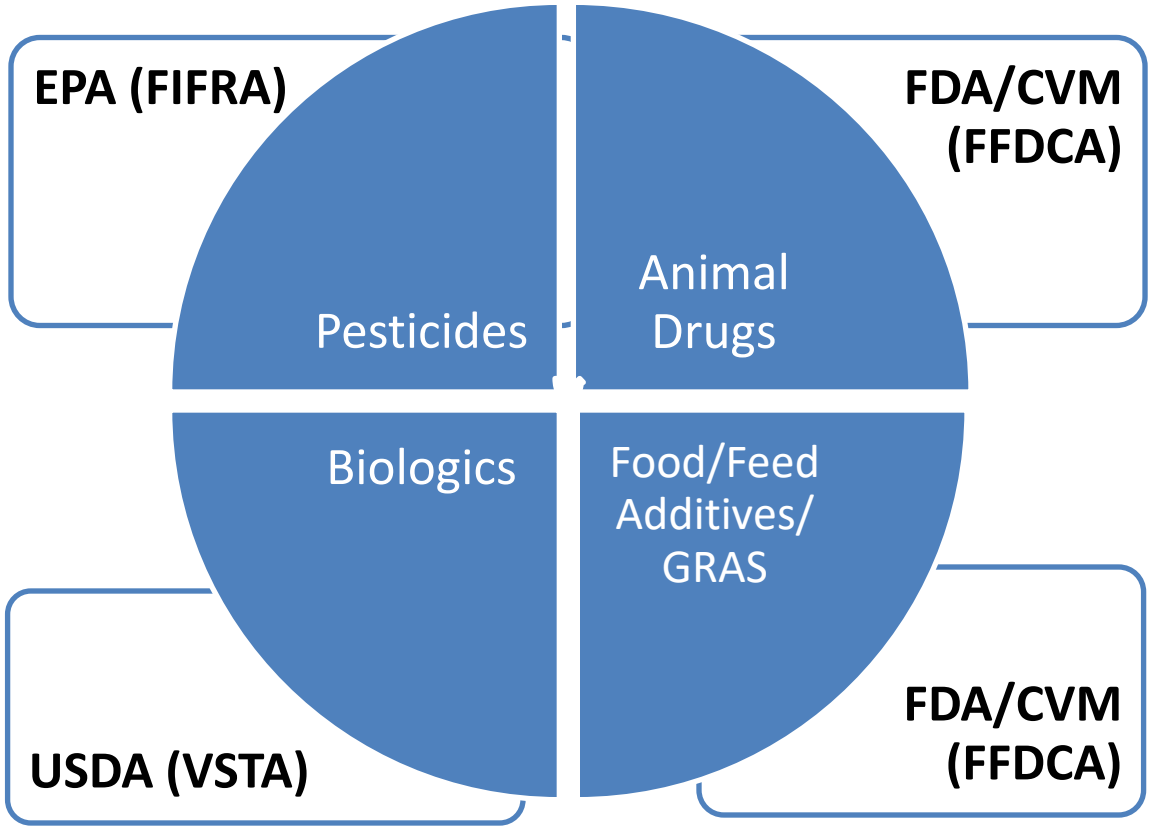
Purpose and Scope

Discuss how USDA and FDA determine regulatory oversight of animal products as biologicals, including phages, under the Virus-Serum-Toxin Act (VSTA), or as drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA).

Jurisdiction of animal products in the U.S.



Memorandum of Understanding (MOU) 225-05-7000

- Agreement that reflects the understanding between CVB and CVM regarding procedures and responsibilities for resolving regulatory oversight issues or questions concerning the regulation of certain animal products.

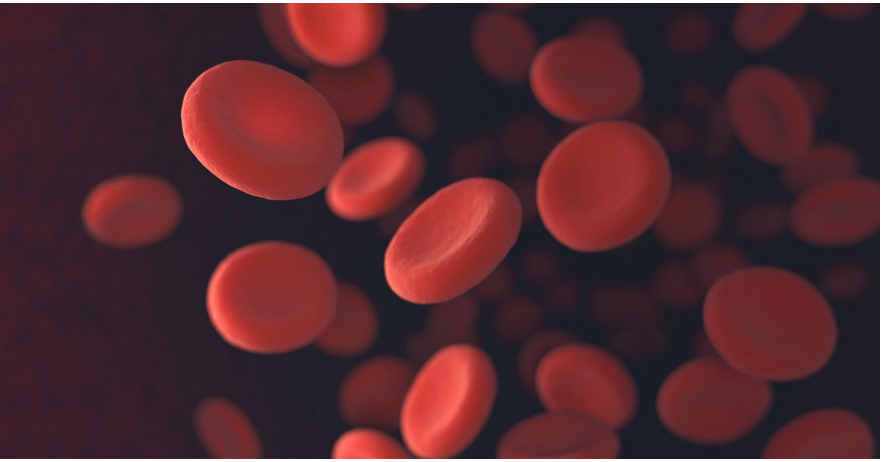
- In addition to outlining statutory authorities, it specifies the purpose of a standing Committee formed to evaluate regulatory oversight decisions.

Animal products or articles regulated by CVM

- Products intended for animals that meet the definition of a food, drug, or device.

- CVM regulates animal drug products intended
  - for use in the diagnosis, cure, mitigation, treatment, or prevention of animal disease if the primary mechanism of action is not immunological or is undefined (unknown) and those intended
  - to affect the structure or function of the body of animals (21 USC 321(g), paraphrase).

- CVM regulates biological products as animal drugs when they are not produced and distributed in full conformance with the Virus-Serum-Toxin Act (VSTA) and its implementing regulations (9 CFR, Chapter I, Subchapter E).

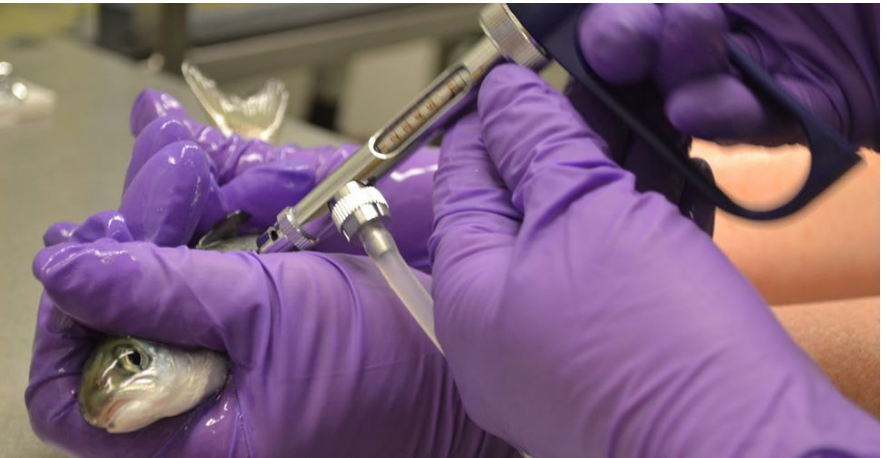


Examples of products regulated by CVM

- Antimicrobials
- Anthelminthics/antiprotozoals
- Corticosteroids
- Hormones
- Stem cells
- Steroidal and non-steroidal anti-inflammatories
- Whole blood, transfusion, and clotting products except serum and plasma products for passive transfer of immunity
- Products that are intended for use to treat disease, if the primary mechanism of action is not immunological or is undefined (unknown)
- Certain diagnostic products
- Refer to the MOU for additional examples.

Animal products or articles regulated by CVB

- CVB regulates biological products under the Virus-Serum-Toxin Act (VSTA) with definitions in 9 CFR Part 101.
- Biological products are those which are "intended for use in the treatment of animals and which act[s] primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response."



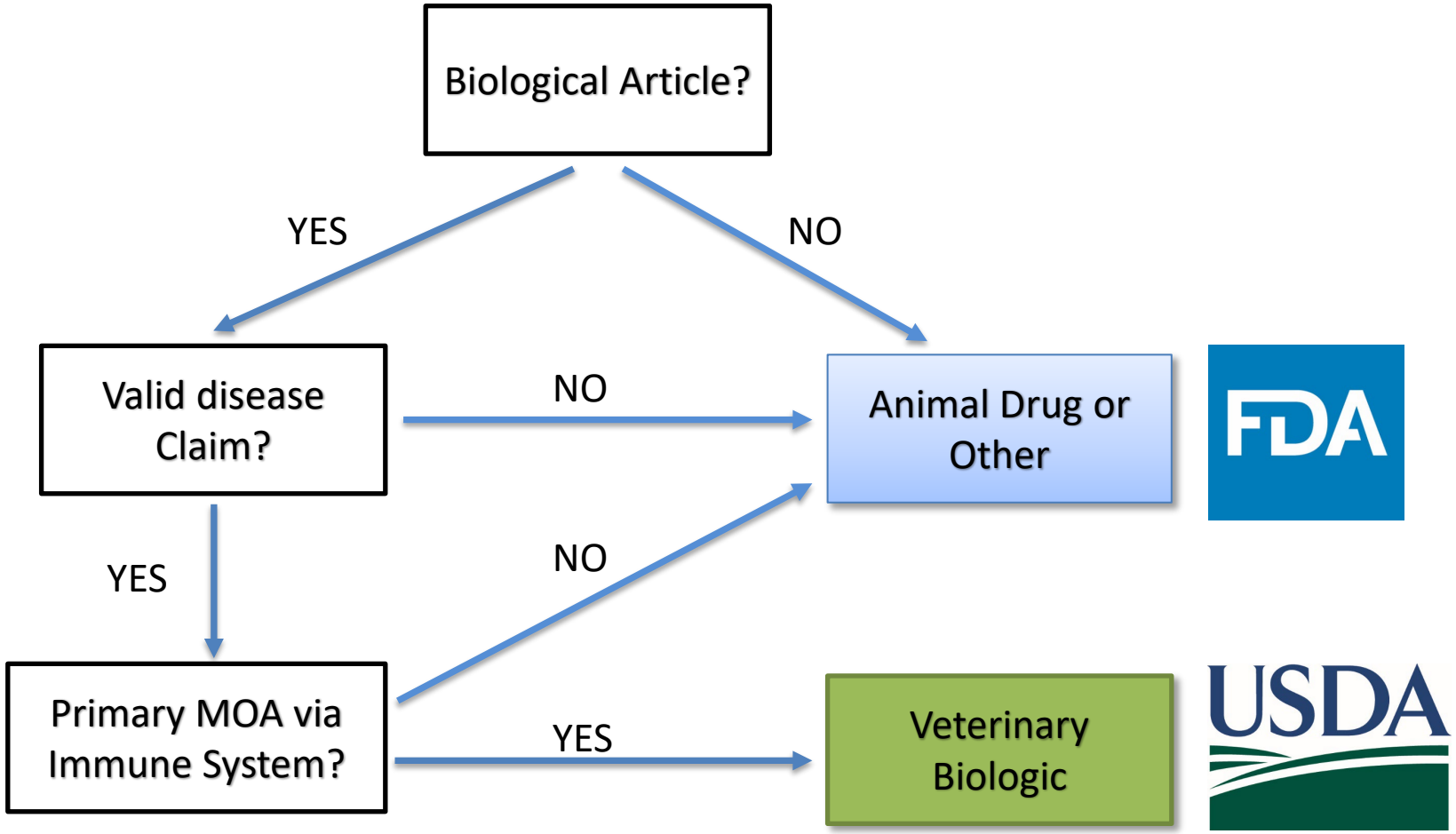
Examples of products regulated by CVB

- Vaccines
- Toxoids
- Antitoxins
- Antibodies
- Immunomodulators
- Immune cells
- Allergens
- Certain diagnostic products

Joint agency standing committee

- The CVM/CVB Jurisdiction Committee, made up of subject matter experts from CVB and CVM, is tasked with evaluating new inquiries concerning animal products on a case-by-case basis to determine which agency has regulatory oversight.

Key Decision Points in the Jurisdiction Process



MOA = Mechanism of Action

Where to submit a jurisdiction request

- Can be submitted to either agency, best practices are to submit to both.
- CVM: by email to: AskCVM@fda.hhs.gov
- CVB: by hard copy to:

  Center for Veterinary Biologics
  1920 Dayton Avenue
  Ames, Iowa 50010

What to include in a jurisdiction request

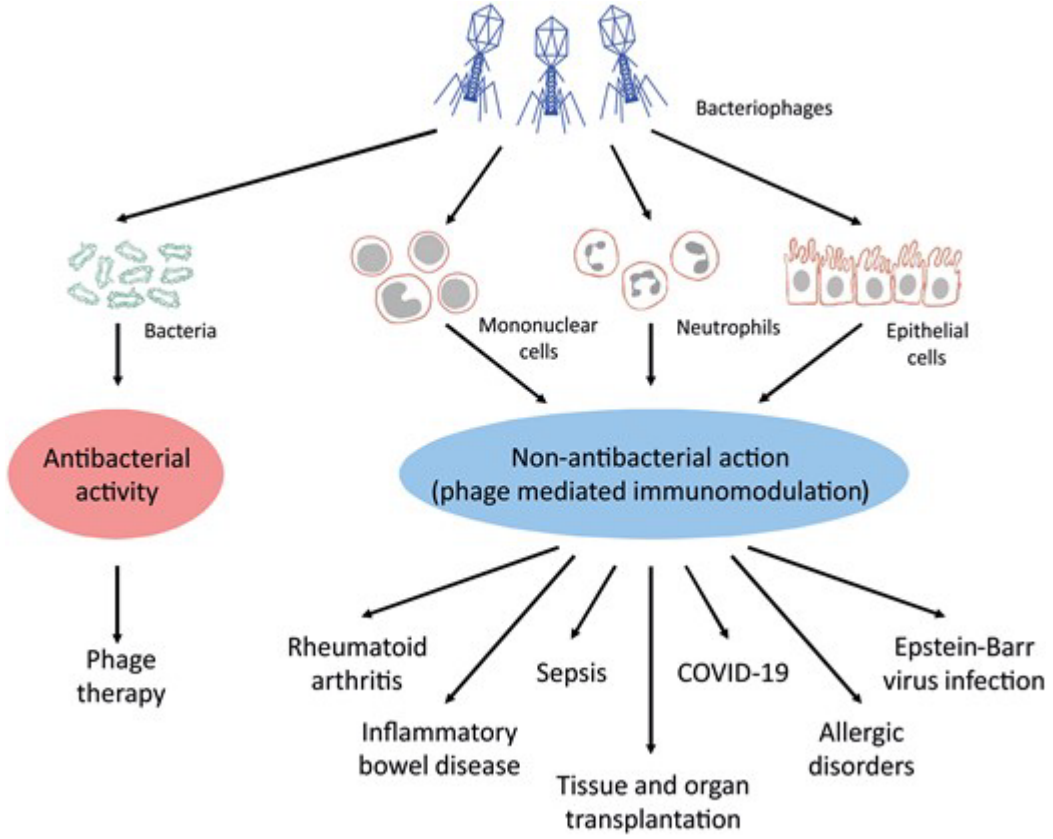
- Contact information for firm and requestor
- Detailed description of the product
- Detailed information on the proposed or known mechanism of action
  - Include summary of data supporting mechanism of action
- Detailed information on the proposed intended use(s) including summary of data supporting intended use
- Any other pertinent information
- Permission for USDA CVB and FDA CVM to share information across agencies

Timeline

- The Committee interacts as frequently as needed to address regulatory oversight questions.
- The typical response time for Committee decisions is 90 days, but this can vary.
- Factors that could impact the Committee response time include:
  - Whether the product uses or is produced by a novel technology
  - Whether sufficient information about the product was provided in the inquiry
  - Whether changes are made to the information about the product after your inquiry was submitted.
- NOTE – Changes to the product's intended uses (including claims) after your inquiry may impact which agency has regulatory oversight.

Phages

- Oversight of phages will depend on the intended use/label claim of the phage as well as the mechanism of action.
- In general, phages that act directly on bacteria are drugs under FDA oversight because they are acting as antimicrobials.
- As new applications for phages arise, the Committee will consider oversight on a case-by-case basis.



Andrzej Górski, Ryszard Międzybrodzki, Ewa Jończyk-Matysiak, Monika Kniotek, Sławomir Letkiewicz, Therapeutic Phages as Modulators of the Immune Response: Practical Implications, *Clinical Infectious Diseases*, Volume 77, Issue Supplement_5, 1 November 2023, Pages S433–S439, https://doi.org/10.1093/cid/ciad483

Additional resources

- MOU
  https://www.fda.gov/about-fda/domestic-mous/mou-225-05-7000
- What does FDA regulate?
  https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate
- Regulation of animal biologicals
  https://www.fda.gov/animal-veterinary/products/animal-biologicals
- USDA Center for Veterinary Biologics
  https://www.aphis.usda.gov/veterinary-biologics

Questions?

- Committee Liaison Contact Information

  – Emily Cornwell, DVM, PhD, CertAqV
  AskCVM@fda.hhs.gov

  – Bruce Thomsen, DVM, PhD, DACVP
  CVB@usda.gov