Charter for the jurisdiction determination process of the USDA CVB/FDA CVM Jurisdiction Committee

Updated December 2024

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I. INTRODUCTION

Purpose

This document details the common understanding between USDA/APHIS/CVB (hereinafter "USDA CVB") and HHS/FDA/CVM (hereinafter "FDA CVM") for a collaborative process by which both Agencies will make jurisdictional determinations on the regulation of products as either veterinary biologics under the Virus-Serum-Toxin Act (VSTA) or drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA). This document is intended to be used in conjunction with the Memorandum of Understanding (MOU) between USDA CVB and FDA CVM[1] and is provided to the public to increase transparency of the committee's determination process.

Scope

This document applies to biological articles intended for use in animals. The USDA CVB/FDA CVM Jurisdiction Committee (hereafter, "Committee") determines oversight for products that raise a jurisdictional issue. The Committee also facilitates communication between USDA CVB and FDA CVM. This document describes the Committee's decision-making process.

Regulatory and Statutory authorities

According to 21 CFR § 510.4, new animal drugs in full conformance with VSTA and its implementing regulations will not be subject to the new animal drug approval requirements in

[1] Memorandum of Understanding (MOU) between the Animal and Plant Health Inspection Service, United States Department of Agriculture and the Food and Drug Administration, Department of Health and Human Services; APHIS Agreement #04-9100-0859-MU; FDA Serial #225-05-7000; 02/04/2013. Available at: https://www.fda.gov/about-fda/domestic-mous/mou-225-05-7000 and at https://www.aphis.usda.gov/veterinary-biologics/regulations-guidance/mou-cvb-fda.

Section 512 of the FFDCA. Therefore, jurisdictional determinations are generally based on whether a product meets the definition of a veterinary biologic under VSTA.

Definitions

All definitions in this section apply only for the purpose of this document and do not necessarily reflect the Agencies' definitions of these terms as used elsewhere.

Biological article: Elements and components related to natural processes of living things. Although both Agencies regulate biological articles, the characteristics of a particular product determines which of the two Agencies has jurisdiction over that specific product.

Biological product: A product that is regulated by USDA CVB because it meets the above definition of a biological article, acts primarily through the immune system, and is intended to diagnose, cure, mitigate, treat, and/or prevent disease in animals.

FDA-regulated drug: A product that is regulated by FDA CVM and is subject to the regulatory requirements of a new animal drug because it does not meet the definition of a biological product above. This includes products intended to affect the structure and/or function of an animal.

Firm: The manufacturer, sponsor, or developer that is legally responsible for the product.

Intended use/label claim: Because USDA CVB looks at the label claim and FDA CVM looks at intended use when assessing products under their respective jurisdictions, for the purposes of this document, the phrase "intended use/label claim" incorporates both of these assessments. For the purposes of this document, the phrase is defined as the objective intent of a product determined based on factors such as the intended use of the product in the target species under conditions of use and the product's labeling.

Product: Article and components that will be marketed.

II. JURISDICTION DETERMINATION PROCESS

The flowchart below (Figure 1) is intended to provide an overview of the general jurisdictional determination process of the Committee. The Committee will conduct an initial review to determine whether there is sufficient and scientifically valid information provided in the request to make a jurisdictional determination. At any point in the process, the Committee may ask for supplemental information.

A. Criteria for determining jurisdiction

The following criteria are used to determine jurisdiction for products presented to the Committee.

i. Is the material a biological article?

Biological articles include but are not limited to: vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, cytokines, antigenic or immunizing components of live organisms, and diagnostic components. They can be of natural or synthetic origin. In general, biological articles are large, complex molecules or mixtures of molecules. Biological articles could be regulated by USDA CVB or FDA CVM

depending on the additional criteria below; however, a product must be a biological article in order to be regulated by USDA CVB.

ii. Does the Interagency Memorandum of Understanding (MOU) adequately address the biological article?

The MOU between FDA CVM and USDA CVB describes the regulatory authority of each Agency. The MOU also includes a description of established product jurisdictions. When determining jurisdiction of a biological article, the Committee adheres to the established product jurisdiction described in the MOU and summarized below.

1. Biological articles intended for use in animals regulated by USDA CVB as biological products are those articles that:[2]
   - are intended to diagnose, cure, mitigate, treat or prevent disease in animals, and work primarily through the immune system.

2. Biological articles intended for use in animals regulated by FDA CVM as drugs are those articles that:[3] are intended to diagnose, cure, mitigate, treat or prevent disease in animals, but do not meet the criteria for a veterinary biologic listed in A.ii.1. above. This includes products that:
   - have a primary mechanism of action that is not immunological or is undefined, or
   - are intended to affect the structure and/or function of the animal.

iii. What is the biological article's mechanism of action (MOA)?
1. Biological articles regulated by USDA CVB must act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.[4]
2. Biological articles that do not work primarily through the immune system, have an undefined mechanism of action, or lack supporting documentation to demonstrate they work primarily through the immune system are drugs regulated by FDA CVM under the FFDCA.

iv. What is the biological article's intended use/label claim?[5]
1. Biological articles regulated by USDA CVB as biological products are those articles indicated for the treatment of disease. In this regard, "treatment"[6] means the prevention, diagnosis, management, or cure of disease in animals. Similarly, "disease" means a pathological process having a characteristic set of clinical signs. A disease may affect the whole body or any of its parts, and the disease's cause and pathogenesis may be either known or unknown.

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[2] MOU Section III C, 9 CFR § 101.2
[3] MOU Section III C
[4] 9 CFR § 101.2
[5] MOU Section III C, 9 CFR § 101.2.
[6] 9 CFR § 101.2 : "The term treatment shall mean the prevention, diagnosis, management, or cure of diseases of animals."

a. The scope of a disease includes, but is not limited to, any perturbance of baseline health caused by a specific etiologic agent (such as a bacteria or virus) or an immune-mediated cause, or a specifically identified cancer.
b. Examples of intended uses/label claims not consistent with a biological product regulated by USDA CVB include, but are not limited to, the treatment of clinical signs associated with a disease without addressing the underlying cause of disease. Additionally, intended uses/label claims affecting the structure or function of an animal (e.g., fertility, production claims, etc.) are not consistent with a biological product regulated by USDA CVB.

B. Potential outcomes

The following are potential outcomes from the jurisdictional review process:

i. The product is not a biological article and will be regulated as a drug by FDA CVM.
ii. The biological article will be regulated as a biological product by USDA CVB.
iii. The biological article will be regulated as a new animal drug by FDA CVM.
iv. The biological article has multiple intended uses/label claims, one or more of which will be regulated as a biological product by USDA CVB and one or more of which will be regulated as a new animal drug by FDA CVM. In this case:
    1. The firm can choose to separately seek approval from FDA CVM for the new animal drug intended use (s) and licensure from USDA CVB for the biological product label claim(s) concurrently; or
    2. The firm can choose to pursue only the intended use/label claim(s) regulated by a single Agency, developing a single product. The firm may choose to additionally seek licensure/approval from the other Agency for the intended use/label claim(s) that would be regulated by the other Agency at any point.

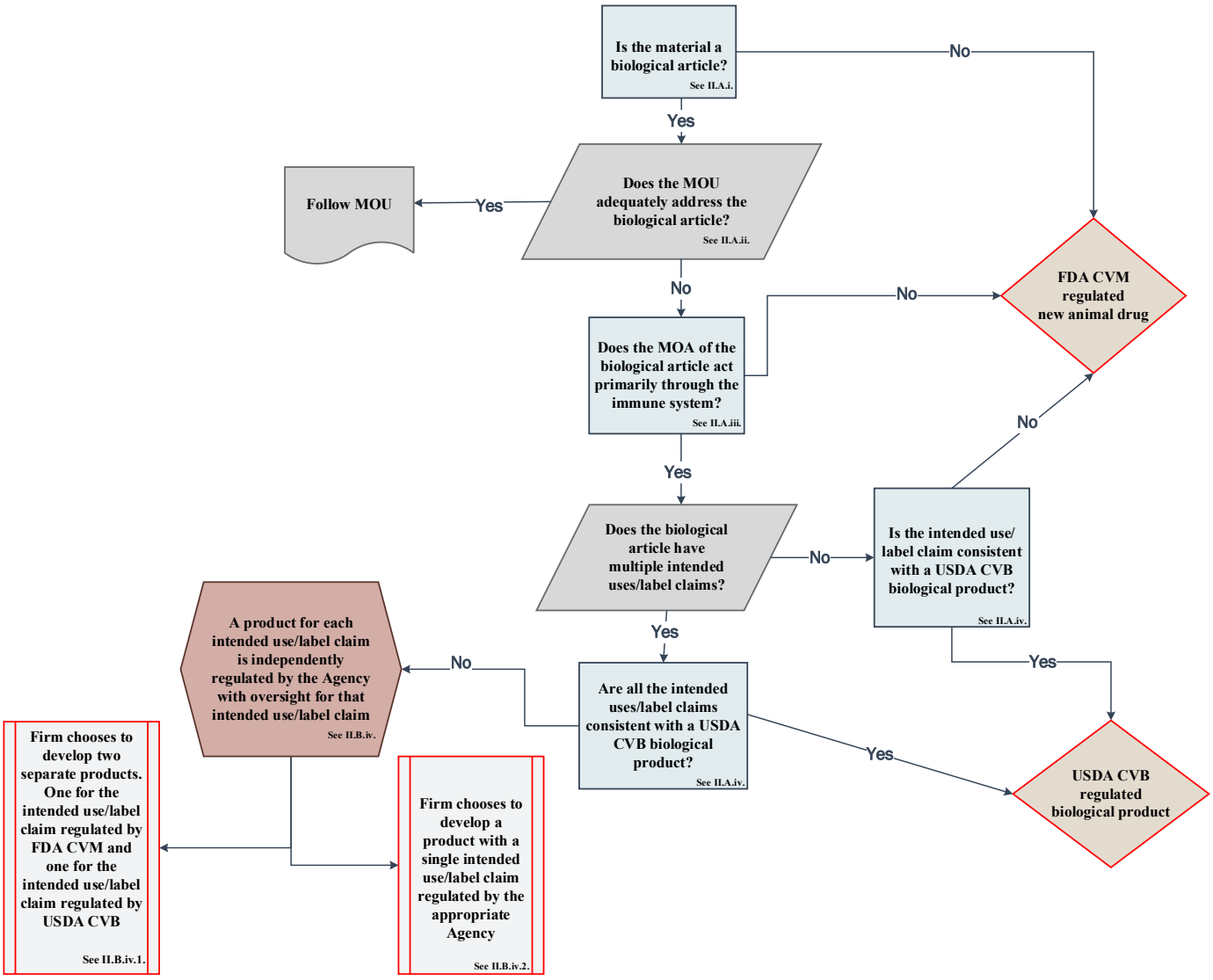

Figure 1. Overview of the USDA CVB/FDA CVM Jurisdiction Committee determination process. Letters in the bottom right-hand corner of boxes refer to the section of text in this document that explains the process in narrative form.

III. REQUESTING A JURISDICTION DETERMINATION

USDA CVB and FDA CVM jointly consider requests submitted to either Agency for a jurisdictional determination on a specific animal product. This information is considered in conjunction with any other information submitted to the agencies as part of an application. Jurisdictional determination requests are typically submitted to FDA CVM at AskCVM@fda.hhs.gov and to USDA CVB at the following address:

1920 Dayton Ave
PO Box 844
Ames, Iowa, 50010.

The firm will receive a response from the Agency with jurisdiction over the product.

The Agencies generally ask the firm, person, or entity submitting the request to provide the following information to ensure timely review:

1. Names and addresses of all legal entities (not individual persons) involved in the manufacture of the product, as well as contact information for the firm and the individual requestor (if different).

2. A detailed description of the product including general principles of manufacture.

3. Animal species for which the product is intended.

4. Detailed information on the proposed or known mechanism(s) of action of the product, including a summary of scientifically valid data in support of the mechanism of action. A narrative description of how the data support the claim that the product does or does not work through the immune system, and how the product affects the underlying pathogenesis of disease. Submitted summary data can be pilot/internal data and/or taken from the scientific literature.

5. Detailed information on the proposed intended use/label claim(s), including a summary of data to support the proposed intended use/label claim(s) and a narrative to describe how the data supports the proposed intended use/label claim(s). Data can be pilot/internal data and/or taken from the scientific literature.

6. If scientific literature is used to support the submission, copies of the referenced papers should be provided to expedite review.

7. Any other pertinent information that may assist in determining jurisdiction.

8. Permission for USDA CVB and FDA CVM to share information across Agencies, including confidential business information, as appropriate to determine which Agency will regulate the product. USDA CVB and FDA CVM agree to protect such confidential information from unauthorized public disclosure as described in the MOU. See e.g., 21 U.S.C. 331(j); 18 U.S.C. 1905; 21 C.F.R. Parts 20 and 21.

IV. RECONSIDERATION PROCESS

In rare cases the Committee may reconsider a previous decision for unlicensed/unapproved products. A reconsideration may be initiated by either the firm or the Committee in the event that there are compelling new circumstances such as new scientifically valid information, or substantial changes in the proposed intended use/label claim that may change jurisdiction. For example, if a firm requests a change to the intended use/label claim of an existing product, the Committee may review the jurisdiction of the revised intended use/label claim. Similarly, if a firm is not able to demonstrate effectiveness of a product for the originally proposed intended use/label claim but elects to pursue a different intended use/label claim (e.g., a change from treating underlying disease to a claim of symptom alleviation) a reconsideration may be warranted. Finally, if new scientific information indicates a product works through the immune

system when the mechanism was previously unknown or undefined, a reconsideration may be warranted. A change in jurisdiction will require licensure/approval with the appropriate Agency. Some data generated may be applicable to both processes, but differences in requirements do exist and the firm is responsible for meeting applicable requirements. The reconsideration process is described in Figure 2.

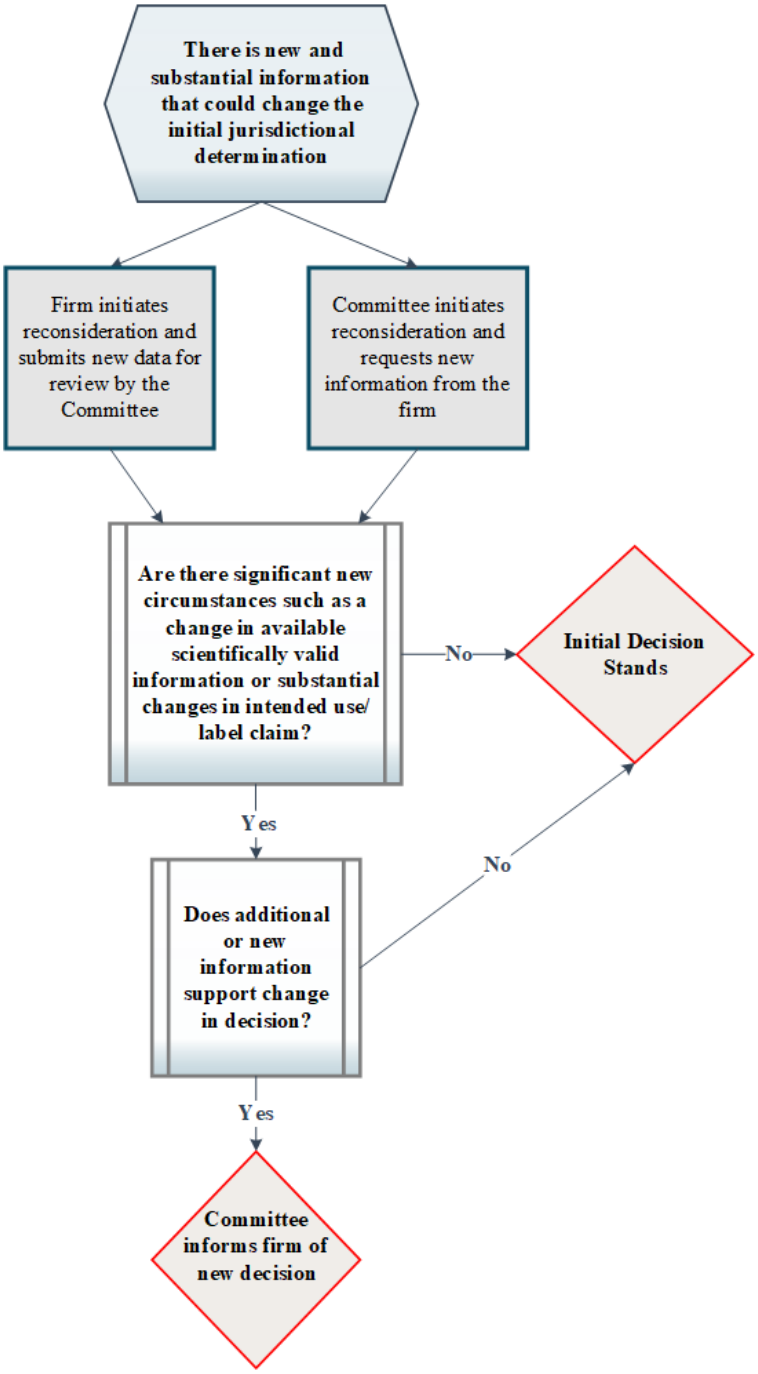

Figure 2. An overview of the USDA CVB/FDA CVM Jurisdiction Committee's reconsideration process.

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