



**VETERINARY EXAMINING BOARD**

**2811 Agriculture Drive, Madison, Wisconsin**

**Contact: Melissa Mace 608-224-4883**

**July 24, 2019**

*The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.*

**AGENDA**

**I. 9:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL**

**II. Introductions**

A. New Member: Dr. Hunter Lang

**III. Approval of the Agenda**

**IV. Approval of Board Meeting Minutes**

A. April 24, 2019

**V. Public Comments**

*Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk.*

**VI. American Association of Veterinary State Boards (AAVSB) Matters**

A. Annual Meeting and Attendees

*September 26<sup>th</sup>-28<sup>th</sup>, 2019 – St. Louis, Missouri*

**VII. Administrative Items**

A. Appointments of Liaisons, Alternates, and Delegates (Where Dr. Johnson Served)

1. Continuing Education
2. Screening Panel
3. Credentialing Committee

B. Guidance Documents

1. Bull Semen Collection
2. Cannabis Products

C. Dispensing of Drugs without a VCPR

D. Updated Board Member Packet

E. WVMA Newsletter – VEB Article

F. Complaint Update 2019

G. Staffing Update

**VIII. Licensing/Exam Inquiries**

**IX. Administrative Code Updates**

- A. VE 7 - Complementary, Alternative and Integrative Therapies
- B. VE 1 - Relating to the Definition of Veterinary Medical Surgery
- C. VE 11 - Update on the Request for Proposals (RFP)
- D. VE 1-11 - Reorganization

**X. Legislative Update**

- A. Wis. Stat. Ch. 89 Legislation: Initial License Fees

**XI. Future Meeting Dates and Times**

- A. October 23, 2019 (9:00AM)

**XII. CONVENE TO CLOSED SESSION**

*CONVENE TO CLOSED SESSION to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.).*

**XIII. Deliberation on Licenses and Certificates**

- A. 19 TECH 001 LB

**XIV. Deliberation on Proposed Stipulations, Final Decisions and Orders**

- A. 18 TECH 008 KC
- B. 17 VET 026 & 18 VET 015 JK
- C. 18 VET 032 LY
- D. 19 VET 012 RE
- E. 19 VET 020 PJ
- F. 19 VET 031 CW

**XV. Review of Veterinary Examining Board Pending Cases Status Report**

**XVI. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

**XVII. Open Session Items Noticed Above not Completed in the Initial Open Session**

**XVIII. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate**

**XIX. Ratification of Licenses and Certificates**

**XX. ADJOURNMENT**

*The Board may break for lunch sometime during the meeting and reconvene shortly thereafter.*

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>M. Mace</b>		2) Date When Request Submitted: 7/10/19  Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
3) Name of Board, Committee, Council, Sections:  Veterinary Examining Board			
4) Meeting Date:  <b>July 24, 2019</b>	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page?  AAVSB – Selection of delegates	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
<p>The Annual meeting for the AAVSB is September 26-28 in St. Louis MO. AAVSB will pay for two delegates from member to attend.</p> <p>See details on the conference at: <a href="https://www.aavsb.org/board-services/annual-meeting/">https://www.aavsb.org/board-services/annual-meeting/</a></p>			
11) <b>Authorization</b>			
Signature of person making this request			Date
Supervisor (if required)			Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda)			Date
<p><b>Directions for including supporting documents:</b></p> <ol style="list-style-type: none"> <li>1. This form should be attached to any documents submitted to the agenda.</li> <li>2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director.</li> <li>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.</li> </ol>			

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

<b>1) Name and Title of Person Submitting the Request:</b>  <b>M. Mace</b>		<b>2) Date When Request Submitted:</b> 7/12/19  Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
<b>3) Name of Board, Committee, Council, Sections:</b>  Veterinary Examining Board			
<b>4) Meeting Date:</b>  <b>July 24, 2019</b>	<b>5) Attachments:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b>	
<b>7) Place Item in:</b> <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b> <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b>	
<p style="text-align: center;"><b>Dr. Johnson served as a liaison in the following capacities:</b></p> <ol style="list-style-type: none"> <li>1. Continuing Education - Primary</li> <li>2. Screening Panel - Member</li> <li>3. Credentialing Committee – Member</li> </ol> <p style="text-align: center;">Does the Board wish to nominate replacements at this meeting or wait to October when Lyn Schuh – CVT is on board, and maybe our final public member?</p>			
<b>11) Authorization</b>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)    Date			
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

<b>2019 ELECTION RESULTS</b>	
Board Chair	Robert Forbes
Vice Chair	Kevin Kreier
Secretary	Diane Dommer Martin

<b>2019 LIAISON APPOINTMENTS</b>	
Education and Exams Liaison	Lisa Weisensel Nesson <i>Alternate:</i> Diane Dommer Martin
Continuing Education Liaison	Philip Johnson <i>Alternate:</i> Lisa Weisensel Nesson
Legislative Liaison	Bruce Berth <i>Alternate:</i> Kevin Kreier
Administrative Rules Liaison	Diane Dommer Martin <i>Alternate:</i> Kevin Kreier
Monitoring	Lisa Weisensel Nesson <i>Alternate:</i> Kevin Kreier
Screening Panel – Change effective April 1, 2019.	Philip Johnson, Lisa Weisensel Nesson, Kevin Kreier, and Diane Dommer Martin
Credentialing Panel	Robert Forbes, Diane Dommer Martin, and Philip Johnson

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request: <b>Angela Fisher, Program and Policy Analyst</b>		2) Date When Request Submitted: 6/25/19	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
3) Name of Board, Committee, Council, Sections: <b>Veterinary Examining Board</b>			
4) Meeting Date: <b>July 24, 2019</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Guidance Documents</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
<p><b>Guidance Documents:</b></p> <ul style="list-style-type: none"> <li>- Bull Semen Collection: Updated draft for final approval by the Board</li> <li>- Cannabis Products: First draft for discussion by the Board</li> </ul>			
11) <b>Authorization</b>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
<p><b>Directions for including supporting documents:</b></p> <ol style="list-style-type: none"> <li>1. This form should be attached to any documents submitted to the agenda.</li> <li>2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director.</li> <li>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.</li> </ol>			



## State of Wisconsin

### Veterinary Examining Board

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#### **Guidance Document VEB-GD-001 DRAFT Bull Semen Collection (Electro-Ejaculation)**

Wis. Stat. § 89.03 (1)  
Wis. Admin. Code § VE 7.02  
7/15/19 DRAFT

#### **Topic**

This guidance document clarifies which procedures involving electro-ejaculation bull semen collection, as listed below, a licensed veterinarian must perform, which procedures may be delegated to a certified veterinary technician, and which procedures may be delegated to an unlicensed assistant.

1. Insert the probe
2. Ejaculate the bull
3. Collect the semen sample
4. Evaluate the semen for concentration, motility, and morphology
5. Measure scrotal circumference
6. Based on the evaluation parameters listed in 4 and 5, give a rating as to semen quality

#### **Relevant Statutes and Administrative Code**

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Admin. Code § VE 1.01 (5) defines “direct supervision” as immediate availability to continually coordinate, direct and inspect personally the practice of another.

Wis. Admin. Code § VE 7.02 (1) (a) limits the diagnosis and prognosis of animal diseases and conditions to veterinarians and prohibits the delegation of such acts to veterinary technicians or other persons not holding such license or permit.

Wis. Admin. Code § VE 7.02 (3) (b) allows veterinarians to delegate to certified veterinary technicians, while under the direct supervision of the veterinarian, the provision of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis, including nonsurgical specimen collection.



Wis. Admin. Code § VE 7.02 (5) (a) allows veterinarians to delegate to unlicensed assistants, while under the direct supervision of the veterinarian, the provision of basic diagnostic studies, including nonsurgical specimen collection.

Wis. Admin. Code § VE 7.02 (6) (b) allows veterinarians to delegate to unlicensed assistants, while under the direct supervision of the veterinarian when the veterinarian is personally present on the premises where the services are provided, the provision of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis.

Wis. Admin. Code § VE 7.02 (8) (c) requires that, when the veterinarian is not required to be personally present on the premises where the delegated services are performed, the veterinarian must be available at all times for consultation either in person or within 15 minutes of contact by telephone, by video conference, or by electronic communication device.

### **Board Position**

The Board determined that steps 1 (insert the probe), 2 (ejaculate the bull), and 3 (collect the semen sample) are acts of nonsurgical specimen collection. As such, a veterinarian may delegate steps 1 through 3 to a certified veterinary technician under the direct supervision of the veterinarian (VE 7.02 (3) (b), Wis. Admin. Code) and/or to an unlicensed assistant under the direct supervision of the veterinarian (VE 7.02 (5) (a), Wis. Admin. Code).

The Board determined that step 4 (evaluate the semen for concentration, motility, and morphology) is within the scope of observations and findings related to animal diseases and conditions to be utilized by a veterinarian in establishing a diagnosis or prognosis. As such, a veterinarian may delegate step 4 to a certified veterinary technician under the direct supervision of the veterinarian (VE 7.02 (3) (b), Wis. Admin. Code) and/or to an unlicensed assistant under the direct supervision of the veterinarian while the veterinarian is personally present on the premises where the services are provided (VE 7.02 (6) (b), Wis. Admin Code).

The Board determined that step 5 (measure scrotal circumference) on its own would not be the practice of veterinary medicine. However, the process of bull semen collection is the practice of veterinary medicine. As such, all steps of the process of bull semen collection must either be performed by a veterinarian or be delegated by the veterinarian to a certified veterinary technician or an unlicensed assistant. A layperson could potentially measure scrotal circumference if the act is not a part of the process of bull semen collection and not a part of any other process that is the practice of veterinary medicine.

The Board determined that step 6 (based on the evaluation parameters listed in 4 and 5, give a rating as to semen quality) is a diagnosis. As such, step 6 is limited to veterinarians and may not be delegated to or performed by veterinary technicians or other persons not holding such a license or permit (VE 7.02 (1) (a), Wis. Admin. Code).



## State of Wisconsin

### Veterinary Examining Board

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#### Guidance Document VEB-GD-002 DRAFT Cannabis

Wis. Stat. § 89.03 (1)  
Wis. Admin. Code § VE 7.06  
7/15/19 DRAFT

#### Topic

This guidance document clarifies what a veterinarian may and may not do with regards to cannabis products.

#### Definitions

*Cannabis* is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. Federal law divides cannabis into two categories: hemp and marijuana.

*Hemp* is defined by the 7 USC 1639o(1) as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” The 2018 Farm Bill removed hemp from Schedule I of the Controlled Substances Act.

*Marijuana/Marihuana* is defined by 21 USC 802(16) as “all parts of the plant *Cannabis sativa* L., whether grown or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivate, mixture, or preparation of such plant, its seeds or resin,” except for “hemp, as defined in section 1639o of title 7; or the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.” Marijuana/Marihuana is listed in Schedule I of the Controlled Substances Act.

*THC* is an abbreviation of delta-9-tetrahydrocannabinol, a compound of the cannabis plant. Hemp plants contain no more than 0.3 percent THC on a dry weight basis, and marijuana plants contain more than 0.3 percent THC on a dry weight basis.

*CBD* is an abbreviation of cannabidiol, a compound of the cannabis plant. Hemp plants and marijuana plants both contain CBD.

*Hemp Seeds* are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The seeds may pick up trace amounts of TCH and/or CBD during the harvesting and processing when they are in contact with other parts of the plant.

## **Relevant Statutes and Administrative Code**

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Stat. § 89.068 (1) (a) prohibits making extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription.

Wis. Stat. § 89.068 (1) (c) 3. prohibits a veterinarian from prescribing a drug to a client for extra-label use on a patient unless all of the following apply:

- a. A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinary-client-patient relationship.
- b. The veterinarian determines that there is no drug that is marketed specifically to treat the patient's diagnosed condition, or determines that all of the drugs that are marketed for that purpose are clinically ineffective.
- c. The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient will be maintained.
- d. If the patient is a food-producing animal, the veterinarian prescribes a sufficient time period for drug withdrawal before the food from the patient may be marketed.

Wis. Stat. § 89.07 (1) (b) classifies violating any federal or state statute or rule that substantially relates to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Wis. Admin. Code § VE 7.06 (4) classifies violating or aiding and abetting the violation of any law or administrative rule or regulation substantially related to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

## **Federal Law and Regulation**

The 2018 Farm Bill removed hemp from the Controlled Substance Act definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law. The 2018 Farm Bill explicitly preserved the authority of the United States Food and Drug Administration (FDA) to regulate products containing cannabis or cannabis-derived compounds under the Food, Drug and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. It is illegal to market or sell cannabis products in interstate commerce for animal use unless the FDA approves the product for animal use. To date, the FDA has not approved any cannabis product for animal use.

*Drugs:* Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure of the body of humans or animals, is a drug. To date, the FDA has not approved any cannabis-containing, cannabis-derived, or cannabis-related drugs for animal use. The FDA has approved one cannabis-derived (Epidiolex) and three cannabis-related (Marinol, Syndros, and Cesamet) prescription drugs for human use. The Animal Medicinal Drug Use Clarification Act (AMDUCA)

permits veterinarians to prescribe extra-label uses of FDA approved human and animal drugs for animals under certain conditions. Among other limitations, extra-label use of a drug is only allowed in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

*Foods:* All food ingredients must be approved by the FDA as either a food additive or as Generally Recognized as Safe (GRAS). The FDA also recognizes ingredients listed in the Official Publication of the Association of American Feed Control Officials (AAFCO). To date, neither the FDA nor AAFCO have approved any cannabis-containing or cannabis-derived foods for animal use. The FDA has approved three cannabis products as GRAS for human use only: hulled hemp seed, hemp seed protein powder, and hemp seed oil.

*Supplements:* The definition of dietary supplement only applies to human products. All products for animal use are classified as either foods or drugs and must be FDA approved. CBD and THC are the active ingredients in FDA approved human prescription drugs, so all products containing CBD or THC are classified as drugs.

See the attached FDA documents for additional information: “Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds,” dated May 31, 2019, and “FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers,” dated April 2, 2019. See the FDA website at [www.fda.gov](http://www.fda.gov) for the latest information regarding FDA regulation of cannabis-containing and cannabis-derived products.

## **Board Position**

*This is a draft document. The topic is on the agenda for the July 24<sup>th</sup> board meeting.*

Administering, prescribing, or dispensing drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Stat. § 89.07 (b) and Wis. Admin. Code § VE 7.06 (4)).

Referring or recommending drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Admin. Code § VE 7.06 (4)).

### *Questions for the Board:*

Are there times when a veterinarian can or should discuss cannabis products with their clients? If so, are there any guidelines for these types of discussions?

- For example:
  - If the client has already given the patient an unapproved product?
  - If the client expresses an intention to give the patient an unapproved product?
  - If the veterinarian’s discussion is focused on avoiding negative consequences for the patient and does not make a referral or recommendation to use unapproved products?
  - If a client is giving the patient unapproved products, or expresses an intention to give the patient an unapproved product, and the veterinarian refuses to discuss or does not discuss concerns (such as FDA status), would there be a concern for the veterinarian’s license?

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IN THIS SECTION



SPEECH

# Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

MAY 31, 2019

**Speech by**

Norman E. "Ned" Sharpless, MD

Acting

Commissioner of Food and Drugs - Food and Drug Administration

White Oak, MD

*(Remarks as prepared for delivery)*

Thank you for joining FDA today for this public hearing titled “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds”.

I am pleased to see that there is such interest in this topic. We have over 500 people registered to attend in person, over 800 people registered to join us remotely, and over 100 speakers on today’s agenda presenting on this topic.

We encourage all stakeholders – presenters, attendees, and those unable to participate in today’s hearing – to submit comments to our docket on this topic, which is open until July 2, 2019.

Docket comments will help inform FDA as we consider the important policy options related to the regulation of products containing cannabis or cannabis-derived compounds.

It is important to note that the FDA's role in the regulation of products containing cannabis or cannabis-derived compounds is not new.

Cannabis contains more than 80 biologically active chemical compounds, including the two best known compounds, delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

If one of these compounds, or the plant itself, is added to a food or cosmetic, marketed as a drug, or otherwise added to an FDA-regulated product in interstate commerce, then it falls within FDA's jurisdiction. As I said, this is nothing new for FDA.

At the same time, some relevant laws have changed. First, some states have changed their laws to allow for "medical" use of marijuana or CBD, and others have begun allowing for recreational marijuana use, or decriminalized recreational marijuana possession.

Second, certain federal laws have changed as well. Parts of the Cannabis sativa plant have been controlled under the Federal Controlled Substances Act, or CSA, since 1970 under the drug class "Marihuana."

Marihuana is included in Schedule I of the CSA – the most restrictive schedule – due to its potential for abuse, largely attributable to the psychoactive effects of THC, and the absence of a currently accepted medical use in the United States.

Late last year, the federal scheduling of cannabis changed. The Agriculture Improvement Act of 2018, or the Farm Bill, removed hemp – meaning cannabis or derivatives of cannabis with a very low THC content (below 0.3% by dry weight) – from the CSA's definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law.

As these laws have changed, FDA's authorities have become more relevant.

The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds. In doing so, Congress recognized FDA's important public health role with respect to all the products it regulates – including when those products are or contain cannabis ingredients.

FDA treats substances derived from cannabis just like we do any other substances, and they are subject to the same authorities as any other substance.

Under FDA's authorities, the relevant legal requirements vary depending on which type of product we're talking about.

For example, if a product is being marketed as a drug – meaning, for example, that it's intended to have a therapeutic effect such as treating a disease or affecting the body's structure or function – then it's regulated as a drug, and it generally cannot be sold without FDA approval.

FDA has approved several drug products that contain compounds found in cannabis.

These include EPIDIOLEX, which contains CBD, for the treatment of specific types of seizures in certain pediatric patients, and MARINOL and SYNDROS, which contains dronabinol, a synthetic THC, for uses including the treatment of anorexia in patients with AIDS.

These drugs have important therapeutic value, and it is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis.

Food, including dietary supplements, is regulated differently, but with the same overarching goal of protecting consumers.

We know that American consumers depend on FDA to help make sure that the food they eat, and that they serve to their families, is safe. We do this through a number of requirements.

For example, while we don't generally require foods to be approved by FDA before coming to market, we do require that a new food additive be approved as safe by FDA before being put in the food supply, unless the substance is generally recognized as safe, or GRAS.

This requirement applies to cannabis-derived ingredients, just as it does to any other substance. Americans deserve to know that substances being added to their foods are safe, regardless of the source.

I will note that several cannabis-derived substances have already come to market through the GRAS pathway.

In December, FDA announced that we completed our evaluation of GRAS notices for three hemp seed ingredients and had no objection to their being marketed in human foods for certain uses without approval, provided they comply with all other requirements.

As I mentioned earlier, however, some compounds found in cannabis – specifically, CBD and THC – have been studied and even approved as drugs. It's important to note that the Federal Food, Drug & Cosmetic Act prohibits adding drugs to human or animal food in interstate commerce.

That includes both substances that have been approved as drugs, as well as compounds for which substantial clinical investigations have been instituted. Similarly, the law excludes these products from the statutory definition of a dietary supplement.

Based on the information available to FDA, we have concluded that these provisions apply to CBD and THC. And while there is an exception when the substance was marketed as a food or dietary supplement before it was studied as a drug, we have concluded that that is not the case for CBD or THC.

What that means is that, under current law, CBD and THC cannot lawfully be added to a food or marketed as a dietary supplement.

Although the law says that FDA can issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance.

So, if we were thinking about doing that for a substance like CBD, it would be new terrain for the FDA.

There are important reasons to generally prohibit putting drugs in the food supply. When FDA approves a drug, we carefully evaluate the risks and benefits of a specific formulation, dosage form, and strength for a particular population.

Often, we conclude that to be safely used, it requires a prescription or other medical supervision to help protect against potentially dangerous misuse.

THC and CBD are no exception.



There are real risks associated with both those substances and critical questions remain about the safety of their widespread use in foods and dietary supplements, as well as other consumer products – including cosmetics, which are subject to a separate regulatory framework.

And given the new interest in marketing cannabis products across the range of areas FDA regulates, we will need to carefully evaluate how all these pieces fit together in terms of how consumers might access cannabis products.

Nowhere is this truer than with CBD. While we have seen an explosion of interest in products containing CBD, there is still much that we don't know.

Prior to the 2018 Farm Bill, population-based research mostly included cannabis-focused observations in aggregate, rather than specific to CBD.

When hemp was removed as a controlled substance, this lack of research, and therefore evidence, to support CBD's broader use in FDA-regulated products, including in foods and dietary supplements, has resulted in unique complexities for its regulation, including many unanswered questions related to its safety.

For example, how much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy, and also consumes some CBD oil? How much is too much? How will it interact with other drugs the person might be taking? What if she's pregnant? What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods?

These and many other questions represent important and significant gaps in our knowledge.

To help us evaluate these questions, as well as potential pathways for CBD products, FDA has formed an internal working group to address these data gaps specifically. You'll be hearing more from this group in the months to come.

FDA is aware that some companies appear to be marketing products containing cannabis and cannabis-derived compounds in ways that violate the law.

FDA has issued warning letters to companies selling unapproved CBD products.

Our biggest concern is the marketing of products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat, or cure serious diseases, such as cancer, in the absence of requisite approvals.

Selling unapproved drug products with unsubstantiated therapeutic claims is a violation of the law, and puts patients at risk.


Patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

That being said, the agency does not have a policy of enforcement discretion with respect to any CBD products.

There are lots of questions we will need to answer to ensure that FDA is taking an appropriate, well-informed, and science-based approach to the regulation of cannabis and cannabis derivatives, including CBD.

We hope that this meeting, and the comments submitted to our public docket, will help us as we try to approach this issue in an informed way. This hearing is an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products.

I thank you all for taking the time to join us today and your contributions toward this important topic. We have a full agenda....

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# FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

Over the past decade, there has been a growing interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.

## Latest News

In order to inform the regulatory path forward, FDA is holding a **[public hearing \(/NewsEvents/MeetingsConferencesWorkshops/ucm634550.htm\)](#)** on May 31, 2019, for stakeholders to share their experiences and challenges with products containing cannabis and cannabis-derived compounds, including information and views related to the safety of such products, as well as to solicit input relevant to the agency's regulatory strategy related to existing products. As part of that hearing, FDA is opening a docket for the public to submit comments.

Below are a number of frequently asked questions and answers on this topic.

1. **[What are cannabis and marijuana?](#)**
2. **[How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?](#)**
3. **[Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?](#)**
4. **[Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?](#)**
5. **[Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?](#)**
6. **[What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?](#)**
7. **[Has the agency received any adverse event reports associated with cannabis use for medical conditions?](#)**

8. Is it legal for me to sell CBD products?
9. Can THC or CBD products be sold as dietary supplements?
10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?
11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?
12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?
13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?
14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?
15. Can I import or export cannabis-containing or cannabis-derived products?
16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?
17. Does the FDA object to the clinical investigation of cannabis for medical use?
18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?
19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?
20. Does the FDA have concerns about administering a cannabis product to children?
21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?
22. What does the FDA think about making CBD available to children with epilepsy?
23. What should I do if my child eats something containing cannabis?
24. I've seen cannabis products being marketed for pets. Are they safe?
25. Can hemp be added to animal food?
26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

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## 1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

## 2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

## 3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

A. To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex, which contains a purified form of the drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

## 4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

A. No. There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses, and we have issued several [warning letters \(/NewsEvents/PublicHealthFocus/ucm484109.htm\)](https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm) to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular

drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process (see Question #16).

## **5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?**

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 **[Guidance for Industry: Botanical Drug Development](https://www.fda.gov/oc/ohrt/industry-guidance-botanical-drug-development)** (**[/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM458484.pdf](https://www.fda.gov/oc/ohrt/industry-guidance-botanical-drug-development)**)

provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the **National Cancer Institute (<https://www.cancer.gov/>)** (NCI) and **National Institute on Drug Abuse (<https://www.drugabuse.gov/drugs-abuse/marijuana/nih-research-marijuana-cannabinoids>)** (NIDA).

#### **6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?**

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of cannabis and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of cannabis products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of cannabis and its derivatives, so that we can provide information on Federal and scientific standards.

#### **7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?**

A. The agency has received reports of adverse events in patients using cannabis or cannabis-derived products to treat medical conditions. The FDA reviews such reports and will continue to monitor adverse event reports for any safety signals, with a focus on serious adverse effects.

Information from adverse event reports regarding cannabis use is extremely limited; FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using cannabis and its constituents can come from clinical trials that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of cannabis and its constituents is needed. Clinical trials of cannabis conducted under an IND application could collect this important information as a part of the drug development process.

#### **8. Is it legal for me to sell CBD products?**

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

#### **9. Can THC or CBD products be sold as dietary supplements?**

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally must notify FDA about these ingredients (see section 413(d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to [Current Good Manufacturing Practices \(CGMPs\) \(/Food/GuidanceRegulation/CGMP/ucm079496.htm\)](https://www.fda.gov/oc/ohrt/Current%20Good%20Manufacturing%20Practices%20(CGMPs)%20(Food/Guidance%20Regulation/CGMP/ucm079496.htm) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

**10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to**



**which THC or CBD has been added?**

A. No. Under section 301(II) of the FD&C Act [21 U.S.C. § 331(II)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(II) (2) of the FD&C Act [21 U.S.C. § 331(II)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(II), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

**11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?**

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution. CBD is the active ingredient in the approved drug product, Epidiolex.

The existence of substantial clinical investigations regarding THC and CBD have been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex. (See [Sativex Commences US Phase II/III Clinical Trial in Cancer Pain \(https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iii-clinical-trial-cancer-pain\)](https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iii-clinical-trial-cancer-pain) [ⓧ \(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm\)](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm))

## 12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?

A. In December 2018, FDA [completed its evaluation \(/Food/NewsEvents/ConstituentUpdates/ucm628910.htm\)](http://www.fda.gov/food/food-news-events/constituent-updates/ucm628910.htm) of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices related only to the use of these ingredients in human food. To date, FDA has not received any GRAS notices for the use of hemp-derived ingredients in animal food (see Question #25).

Hemp seeds are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high."

The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food.

## 13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be

used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer complaint coordinator. For more information, please see the FDA's webpage on how to [report a cosmetic-related complaint \(/Cosmetics/ComplianceEnforcement/AdverseEventReporting/default.htm\)](#).

#### **14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?**

A. The FDA has sent [warning letters \(/NewsEvents/PublicHealthFocus/ucm484109.htm\)](#) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

#### **15. Can I import or export cannabis-containing or cannabis-derived products?**

A. [General information about the import/export of drug products regulated by FDA \(/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm\)](#) can be found online here. The [Drug Enforcement Administration \(https://www.dea.gov/\)](#) (DEA) is the federal agency responsible for enforcing the controlled substance laws and regulations in the U.S. and, as such, should be consulted with respect to any regulations/requirements they may have regarding the import or export of products containing cannabis. Please see here for [information about importing or exporting food ingredients \(/Food/GuidanceRegulation/ImportsExports/default.htm\)](#).

Regarding imports, if it appears that an article is adulterated, misbranded, in violation of section 505 of the FD&C Act, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ii) of the FD&C Act, such article will be refused admission (see section 801(a)(3) of the FD&C Act [21 U.S.C. § 381(a)(3)]).

### **Research and Expanded Access**

#### **16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?**

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of IND of INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.
- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also **may allow additional growers** (<https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to>) to register with the DEA to produce and distribute cannabis for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

## 17. Does the FDA object to the clinical investigation of cannabis for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from cannabis. The FDA supports the conduct of that research by:

1. Providing information on the process needed to conduct clinical research using cannabis.
2. Providing information on the specific requirements needed to develop a drug that is derived from a plant such as cannabis. In December 2016, the FDA updated its **Guidance for Industry: Botanical Drug Development (/downloads/Drugs/GuidanceComplianceRegulatory-Information/Guidances/UCM458484.pdf)**, which provides sponsors with guidance on submitting IND applications for botanical drug products.
3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.

4. Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's [Small Business and Industry Assistance group \(/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm\)](#).

**18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?**

A. [Expanded access \(/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm\)](#) is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

**19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?**

A. [Information for patients on Right to Try \(/ForPatients/Other/ucm625115.htm\)](#) (RTT) is available on our website. RTT is designed to facilitate access to certain investigational drugs through direct interactions between patients, their physicians and drug sponsors – FDA is not involved in these decisions. Sponsors developing drugs for life-threatening conditions are responsible for determining whether to make their products available to patients who qualify for access under RTT. If you are interested in RTT, you should discuss this pathway with your licensed physician. Companies who develop drugs and biologics, also known as sponsors, can provide information about whether their drug/biologic is considered an eligible investigational drug under RTT and if they are able to provide the drug/biologic under the RTT Act.

**Children and Pregnant/Lactating Women**

**20. Does the FDA have concerns about administering a cannabis product to children?**

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

**21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?**

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and

stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

## **22. What does the FDA think about making CBD available to children with epilepsy?**

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

## **23. What should I do if my child eats something containing cannabis?**

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

## **Pets and other Animals**

### **24. I've seen cannabis products being marketed for pets. Are they safe?**

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit [\*\*Reporting Information about Animal Drugs and Devices \(/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm#Drugs and Devices\)\*\*](#) to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

## **25. Can hemp be added to animal food?**

A. All ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, CVM also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and we are unaware of any GRAS conclusions regarding the use of any substances derived from hemp in animal food. [\*\*Learn more about animal food ingredient submissions \(/AnimalVeterinary/SafetyHealth/AnimalFeed-SafetySystemAFSS/default.htm\)\*\*](#) here.

With respect to products labeled to contain "hemp" that may also contain THC or CBD, as mentioned above it is a prohibited act under section 301(l) of the FD&C Act to introduce or deliver for introduction into interstate commerce any animal food to which THC or CBD has been added.

## **26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?**

A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), permits veterinarians to prescribe extralabel uses of approved human and animal drugs for animals under certain conditions. Extralabel use must comply with all the provisions of AMDUCA and its implementing regulation at 21 CFR § 530. Among other limitations, these provisions allow extralabel use of a drug only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship and only in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

In addition, under 21 CFR 530.20, extralabel use of an approved human drug in a food-producing animal is not permitted if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the use. In addition, under 21 CFR 530.20(b)(2), if scientific information on the human food safety aspect of the use of the approved human drug in food-producing animals is not available, the veterinarian must take appropriate measures to ensure that the animal and its food products will not enter the human food supply.

For more information on extralabel use of FDA approved drugs in animals, see [\*\*Extralabel Use of FDA Approved Drugs In Animals \(/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm085377.htm#extralabel\)\*\*](#).

[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. *Clinical Chemistry*. 2010; 56(9): 1442-1450.


[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. *BMJ Open*. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. *Pediatric Research*. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. *Neurotoxicol and Teratol* 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. *Psychopharmacology (Berl)* 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. *Addict Biol* 2007; 12(3-4): 485–495.

[7] **[ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation](https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation)**  
**[\(/https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation\)](https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation)**   
**[\(/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm\)](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

#### Related Information

- **[FDA and Marijuana \(/NewsEvents/PublicHealthFocus/ucm421163.htm\)](/NewsEvents/PublicHealthFocus/ucm421163.htm)**
- **[Marijuana Research with Human Subjects \(/NewsEvents/PublicHealthFocus/ucm421173.htm\)](/NewsEvents/PublicHealthFocus/ucm421173.htm)**

#### More in [Public Health Focus](/NewsEvents/PublicHealthFocus/default.htm) [\(/NewsEvents/PublicHealthFocus/default.htm\)](/NewsEvents/PublicHealthFocus/default.htm)

[Expanded Access \(Compassionate Use\)](/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm)  
[\(/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm\)](/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm)





**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>M. Mace</b>		2) Date When Request Submitted: 7-8-19  Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
3) Name of Board, Committee, Council, Sections:  Veterinary Examining Board			
4) Meeting Date:  <b>July 24, 2019</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page?  <b>Dispensing of Drugs without a VCPR</b>	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:  None	
<p>WVMA submitted a letter requesting the review of the legality of a veterinarian prescribing a drug after examining a pet, and sending the prescription to another veterinarian (who does not have a VCPR and has not examined the veterinarian) to be filled.</p> <p>See attached letters.</p>			
11) <b>Authorization</b>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)    Date			
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

May 6, 2019

VIA EMAIL [Melissa.Mace@wisconsin.gov](mailto:Melissa.Mace@wisconsin.gov)

Ms. Melissa Mace  
Acting Executive Director  
Veterinary Examining Board  
Wisconsin Dept. of Agriculture, Trade & Consumer Protection  
P.O. Box 8911  
Madison, WI 53708-8911

RE: Request for Guidance on Dispensing of Veterinary Prescription Drugs

Dear Ms. Mace:

I write on behalf of the Wisconsin Veterinary Medical Association (WVMA) to request that the Veterinary Examining Board (VEB) issue formal guidance pursuant to Wis. Stat. § 227.112 regarding **the circumstances under which a veterinarian may dispense a drug for a patient of another veterinarian**. More specifically, WVMA seeks guidance from the VEB on the following questions interpreting Wis. Stat. §§ 89.02(6m) and 89.068(1)(c):

Under what circumstances may a veterinarian licensed in Wisconsin dispense a prescription to a patient of another veterinarian?

May a veterinarian dispense a drug for a patient if the dispensing veterinarian has never examined the patient and if the prescription was issued to the dispensing veterinarian by another veterinarian?

Please do not hesitate to contact me with any questions that may arise. Thank you for your attention to this important matter.

Very truly yours,

DeWitt LLP



Jordan K. Lamb

JKL:jav

cc: Ms. Kim Brown Pokorny, Executive Director, Wisconsin Veterinary Medical Assn.  
Attorney J. Wesley Webendorfer, DeWitt LLP



State of Wisconsin  
Veterinary Examining Board

Governor Tony Evers  
Dr. Robert Forbes, DVM, Chair

DATE: July 9, 2019  
TO: Veterinary Examining Board  
FROM: Cheryl Furstace Daniels, Board Counsel  
SUBJECT: Veterinary prescription-writing and dispensing guidance

Attached is a request for guidance from the Wisconsin Veterinary Medical Association (WVMA) regarding the interplay of statutes and rules concerning the writing and dispensing of veterinary prescription medications. The issues to be discussed are as follows:

1. How can the following statutes be read to insure that they are harmonized and give meaning to all of the words?
2. How will the VEB give guidance on this issue until the rule might be amended to more clearly interpret the meaning of the statutory sections?

The applicable statutes and rules are as follows:

**89.02 Definitions.** As used in this chapter, unless the context requires otherwise:

**(3g)** "Dispense" means the act of delivering a drug to a person who may lawfully possess the drug, including the compounding, packaging or labeling necessary to prepare the drug for delivery.

**(6m)** "Prescription" means a written, oral or electronic order from a veterinarian to a pharmacist or to another veterinarian that authorizes the pharmacist or other veterinarian to dispense a drug, or from a veterinarian to a client that authorizes the client to make extra-label use of a drug.

**89.068 Drugs for animal use.**

**(c)** *Prescribing, dispensing and administering requirements for veterinarian.* A veterinarian may not do any of the following:

1. Prescribe for or dispense to a client a veterinary prescription drug or a drug for extra-label use without personally examining the patient unless a veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian determines that the client has sufficient knowledge to administer the drug properly.

**VE 7.06 Unprofessional conduct.** Unprofessional conduct by a veterinarian is prohibited. Unprofessional conduct includes:

**(10)** Selling veterinary prescription drugs without establishing and maintaining a veterinary-patient-client relationship.

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request: <b>Angela Fisher, Program and Policy Analyst</b>		2) Date When Request Submitted: 6/25/19	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
3) Name of Board, Committee, Council, Sections: <b>Veterinary Examining Board</b>			
4) Meeting Date: <b>July 24, 2019</b>	5) Attachments: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Updated Board Member Packet</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
- Informational: The board member packet will be updated and loaded to OnBoard.			
11) <b>Authorization</b>			
Signature of person making this request			Date
Supervisor (if required)			Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda)    Date			
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

<b>1) Name and Title of Person Submitting the Request:</b>  <b>M. Mace</b>		<b>2) Date When Request Submitted:</b> <b>7/12/19</b>  Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
<b>3) Name of Board, Committee, Council, Sections:</b>  Veterinary Examining Board			
<b>4) Meeting Date:</b>  <b>July 24, 2019</b>	<b>5) Attachments:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b>  WVMA newsletter – VEB article	
<b>7) Place Item in:</b> <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b> <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b>	
Division of Animal Health regularly submits articles to the WVMA – We will be submitting one on the VEB covering VE 7, now effective and what it means, and other status' of rules.			
<b>11) Authorization</b>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)    Date			
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

<b>1) Name and Title of Person Submitting the Request:</b>  <b>M. Mace</b>		<b>2) Date When Request Submitted:</b> <b>7-16-19</b>  <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date.</small>	
<b>3) Name of Board, Committee, Council, Sections:</b>  <b>Veterinary Examining Board</b>			
<b>4) Meeting Date:</b>  <b>July 24, 2019</b>	<b>5) Attachments:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b>  <b>Complaint status year to date</b>	
<b>7) Place Item in:</b> <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b> <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b>	
<p>Update on complaint volume and status for 2019.</p>			
<b>11) Authorization</b>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)			
Date			
<b>Directions for including supporting documents:</b>			
1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

## **VEB Complaint Updates – July 2019**

### **2017: 70 total complaints (26 Opened for Investigation)**

- 56 - Veterinarian Complaints (21 opened for investigation)
- 1 - CVT Complaints (0 opened for investigation)
- 13 - Unlicensed Complaints (5 opened for investigation)

### **2018: 99 total complaints (17 Opened for Investigation)**

- 78 - Veterinarian Complaints (11 opened for investigation)
- 9 - CVT Complaints (3 opened for investigation)
- 11 - Unlicensed Complaints (3 opened for investigation)
- 1 - General Complaint (0 opened for investigation)

### **2019, as of July 17, 2019: 75 total complaints (18 Opened for Investigation, 27 cases pending screening review)**

- 65 - Veterinarian Complaints (17 opened for investigation, 24 pending review at screening)
- 2 - CVT Complaints
- 6 - Unlicensed Complaints (1 opened for investigation, 3 pending review)
- 2 – General Complaints

**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>M. Mace</b>		2) Date When Request Submitted:  Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
3) Name of Board, Committee, Council, Sections:  <b>Veterinary Examining Board</b>			
4) Meeting Date:  <b>July 24, 2019</b>	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page?  <b>Staffing Update</b>	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
<p style="margin-left: 40px;">Robert Van Lanen position</p> <p style="margin-left: 40px;">Hiring of LPPA Status update</p> <p style="margin-left: 40px;">Potential to hire an LTE.</p>			
11) <b>Authorization</b>			
Signature of person making this request			Date
Supervisor (if required)			Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda)			Date
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			



**State of Wisconsin  
Department of Agriculture, Trade and Consumer Protection**

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request: <b>Angela Fisher, Program and Policy Analyst</b>		2) Date When Request Submitted: 6/25/19	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date.	
3) Name of Board, Committee, Council, Sections: <b>Veterinary Examining Board</b>			
4) Meeting Date: <b>July 24, 2019</b>	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>Status of Statute and/or Administrative Code Updates</b>	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
<p>Rule related updates:</p> <ul style="list-style-type: none"> <li>A. VE 7 - Complementary, Alternative and Integrative Therapies - <i>Informational</i></li> <li>B. VE 1 - Relating to the Definition of Veterinary Medial Surgery - <i>Informational</i></li> <li>C. VE 11 - Update on the Request for Proposals (RFP) - <i>Informational</i></li> <li>D. VE 1-10 – Reorganization - <i>Proposal to Amend Statement of Scope (Modified scope attached)</i></li> </ul> <p>Legislative update: Wis. Stat. Ch. 89 Legislation: Initial License Fees - <i>Informational</i></p>			
11) <b>Authorization</b>			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)    Date			
<p><b>Directions for including supporting documents:</b></p> <ol style="list-style-type: none"> <li>1. This form should be attached to any documents submitted to the agenda.</li> <li>2. Post Agenda Deadline items must be authorized by a Supervisor and the Executive Director.</li> <li>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.</li> </ol>			

**VEB Rules Estimated Timelines**

Future dates are estimates for the purposes of work planning.  
 Board meeting dates for 2020 onwards are not yet scheduled.  
 Last Updated: 7/9/19

Key	
White	Estimated date
Blue	Actual date
Red	Projection exceeds deadline for adoption
Yellow	Date requires revision

	Topic	Scope #	DATCP Docket #	Clearing-house #	Statement of Scope									Hearing Draft						Final Draft										Deadline for Rule Adoption (Scope Expires)	Rule Effective Date	
					Begin Rule Process	Scope to Governor	Governor Approval of Scope	Scope Published in Register	Materials in Board Agenda	Board Approval Prelim. Hearing & Comment Period	Prelim. Hearing & Comment Period	Materials to Office of Secretary	Board Approve Scope	Hearing Draft Posted for EIA Comment	Materials to Office of Secretary	Board Approval of Hearing Draft	Clearing-house Referral	Clearing-house Comment Received by DATCP	Hearing Dates	Hearing Record Open Until	Materials to Office of Secretary	Board Approval of Final Draft	Final Draft to Governor	Governor Approval of Final Draft	Final Draft Referred to Legis.	Final Draft Referred to Committ.	Committ. Review Period Ends	Final Draft Referred to JCRAR	JCRAR Review Period Ends			Final Adopted Rule Sent to LRB
VE 1	Surgery	SS 025-16	16-VER-1	CR 16-068	x	3/16/16	4/15/16	4/18/16	x	x	x	x	4/27/16	7/22/16	x	10/26/16	10/28/16	11/28/16	11/30/16, VEB Meetings: 7/26/17, 10/25/17, 7/25/18	12/30/16	x	7/25/18	11/21/18	12/27/18	1/7/19	1/16/19, 1/22/19	2/15/19, 2/22/19	2/15/19, 2/27/19	4/30/19	5/31/19	2/4/20	7/1/19
VE 7	CAITs	SS 025-16	16-VER-7	CR 17-084	x	3/16/16	4/15/16	4/18/16	x	x	x	x	4/27/16	x	x	10/25/17	11/30/17	12/19/17	1/10/18, 1/11/18, 1/12/18, 1/9/18	1/31/18	x	2/13/18	3/2/18	8/1/19	8/15/19	8/25/19	10/24/19	11/3/19	1/2/20	1/16/20	2/4/20	3/1/20
VE 1-10	Reorg	SS 100-18			x	6/4/18	8/22/18	8/23/18	x	x	x	x	DATCP 9/20/18, VEB 11/7/18	HOLD																	2/27/21	HOLD
VE 1-11	ReorgRevise				5/17/19	8/1/19	9/30/19	10/14/19	12/22/19	1/12/20	2/11/20	2/20/20	3/12/20	6/10/20	8/18/20	9/8/20	9/15/20	10/5/20	10/12/20	10/26/20	1/3/21	1/24/21	1/31/21	4/1/21	4/15/21	4/25/21	6/24/21	7/4/21	9/2/21	9/16/21	4/14/22	11/1/21

Rule Process Step:	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Step 26	Expiration	Step 27
<b>General Projection Assumptions:</b> (specific projections may vary)	Begin process of drafting scope	60 days after Step 1	60 days after Step 2	14 days after Step 3	21 days before Step 6	90 days after Step 4	30 days after Step 6	21 days before Step 9	30 days after Step 7	90 days after Step 9	21 days before Step 12	90 days after Step 10	7 days after Step 12	20 days after Step 13	7 days after Step 14	14 days after Step 15	21 days before Step 18	90 days after Step 16	7 days after Step 18	60 days after Step 19	14 days after Step 20	10 days after Step 21	60 days after Step 21	10 days after Step 22	60 days after Step 24	14 days after Step 25	30 months after Step 4	1-2 months after Step 26
<b>Notes:</b>					7 days OS + 14 days Board			7 days OS + 14 days Board	90 days after Step 4 if no prelim. hearing		7 days OS + 14 days Board	14, 30, or 60 days comments + 30 days revisions					7 days OS + 14 days Board						30 days, can be extended to 60 days		30 days, can be extended to 60 days			1st of month after 1 full month

# STATEMENT OF SCOPE

## VETERINARY EXAMINING BOARD (VEB)

**Rule No.:** Chs. VE 1 to 11, Wis. Adm. Code (Amended)

**Relating to:** Licensing, Practice Scope, and Standard of Practice for Veterinarians and Veterinary Technicians.

### **1. Description of the objective of the rule:**

The objective of the amended proposed rule is to reorganize existing Veterinary Examining Board (VEB) requirements for purposes of clarity and to codify existing licensing policies and fees.

The VEB proposes to consolidate the eleven current administrative chapters into three subject areas relating to veterinarians, veterinary technicians, and a professional assistance program, and to add a fourth chapter codifying existing procedures.

The VEB also proposes to review, revise, and update the current provisions of the code. This includes aligning the rules to the requirements in Ch. 89, Wis. Stat., and to make technical changes and clarifications as needed.

### **2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:**

2015 Wisconsin Act 55 transferred the VEB from the Department of Safety and Professional Services (DSPS) to the Department of Agriculture, Trade and Consumer Protection (DATCP). However, most of the general licensing rules, specifying the procedures and requirements for all boards under DSPS, were not transferred to DATCP's portion of the Administrative Code, including the rules that specified the amount of license fees, late fees, testing fees, and the like.

The VEB, now under the umbrella of DATCP, continues to employ the same procedures and fees that were employed when the VEB was affiliated with DSPS. The referenced fee structure and administrative practices should be expressly stated in the rule, so that applicants will have notice of what is expected of them and of what fees are requisite to obtain a veterinary license or veterinary technician certification.

Meanwhile, the current rules, consisting of Chapters VE 1 through VE 11, are denominated as follows:

1. Authority and Definitions;
2. Examinations;
3. Licensure by Examination for Veterinarians;

4. Licensure by Endorsement for Veterinarians;
5. Practice Related to Veterinary Schools;
6. Temporary Consulting Permits;
7. Standards of Practice and Unprofessional Conduct for Veterinarians;
8. Certification for Veterinary Technicians;
9. Standards of Practice and Unprofessional Conduct for Veterinary Technicians;
10. Continuing Veterinary Education for Veterinarians and Veterinary Technicians; and
11. Veterinary Professional Assistance Program.

These eleven smaller chapters would be condensed into larger chapters more comprehensive chapters regarding: Veterinarians, Veterinary Technicians, and the Veterinary Professional Assistance Program. Additional chapters may be created if necessary. For example, an additional chapter may be necessary to codify existing procedures. Each chapter would include applicable definitions.

In addition to consolidation, the rules would be revised to align with ch. 89, Wis. Stat., and to make technical changes and clarifications as needed.

All fees will remain the same but will be codified in the proposed rule.

Should the VEB not modify the existing rule, the amounts of fees will not be specified in the code. Furthermore, current requirements relating to veterinarians and veterinary technicians will remain scattered across multiple rules, making the rules more opaque and more difficult to understand. In addition, provisions in the rules that do not align with the statutory language will continue to be confusing for those persons trying to follow both the requirements in the statute and the rules.

**3. Statutory authority for the rule (including the statutory citation and language):**

Under Wis. Stat. ch. 89, the VEB has the authority and an obligation to “promulgate rules... establishing the scope of practice permitted for veterinarians and veterinary technicians.” The VEB “shall review the rules at least once every 5 years to determine whether they are consistent with current practice.” Wis. Stat. § 89.03.

The VEB must “promulgate rules requiring training and continuing education sufficient to assure competency of veterinarians and veterinary technicians in the practice of veterinary medicine” and may “promulgate rules relating to licensure qualifications, denial of a license, certification, or temporary permit, unprofessional conduct, and disciplinary proceedings.” Wis. Stat. § 89.03.

Regarding the authority pertaining to fees, the statutes grant authority to the Department who “shall determine by rule the fees for each initial license, certification, and permit issued.” Wis. Stat. § 89.063.

**4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:**

The Department estimates that it will use approximately .50 FTE staff to develop this rule. That calculation includes time required for investigation and analysis, drafting the rule, preparing related documents, coordinating advisory committee meetings, holding public hearings, and communicating with affected persons and groups. The Department will use existing staff to develop this rule.

**5. Description of all entities that may be impacted by the rule:**

This rule will have a direct impact on veterinarians and veterinary technicians licensed by the VEB.

**6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:**

Pursuant to 9 CFR 160 to 162, a veterinarian must be specifically authorized by the Animal and Plant Health Inspection Service to perform animal disease eradication and control functions under federal animal health laws.

Licensure requirements to practice veterinary medicine are established by each state and should not be affected by federal requirements.

**7. Anticipated economic impact**

The Department expects the proposed rule to have no economic impact or at most a minimal impact.

**Contact Person:** Melissa Mace, Acting Executive Director, Veterinary Examining Board;  
(608) 224-4883

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Melissa Mace, Acting Executive Director  
Veterinary Examining Board

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Date