

Veterinary Medical Board

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MEMORANDUM

DATE	November 15, 2018
TO	Veterinary Medical Board
FROM	Cheryl Waterhouse, DVM, Board President
SUBJECT	Agenda Item 17. Update and Possible Action on Proposed Revisions to Pharmaceutical Compounding – Nonsterile Preparations, General Chapter 795 of the United States Pharmacopeia (USP)

Background

During the [May 2018](#) meeting, Dr. Richard Sullivan advised the Veterinary Medical Board (Board) that the US Pharmacopeia (USP), a non-profit organization that established standards for medication and guidelines for compounding products, was updating their compounding standards which were used when developing the Board compounding regulations. The proposed revisions from USP would restrict clinicians to certain compounding and would impact the proposed regulations.

The Board, American Veterinary Medical Association (AVMA), and California Veterinary Medical Association (CVMA) submitted letters to USP expressing their concerns with the proposed revisions.

Attached are the letters sent by the Board, AVMA, and CVMA. There are no updates at this time; however, the Board's Executive Officer will work with the Board of Pharmacy and the Medical Board of California leadership to gain support of the Board's compounding regulations. The goal is to address any concerns the other boards may have related to the proposed regulations.

Attachment

1. Board letter to USP Regarding Comments to Proposed Changes to USP General Chapter <795> Nonsterile Preparations 2018 Draft
2. CVMA letter to USP Regarding California Veterinary Medical Association Comments on USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations 2018 Draft
3. AVMA letter to USP

Veterinary Medical Board

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June 22, 2018

USP-U.S.
12601 Twinbrook Parkway
Rockville, MD 20852-1790

RE: Comments Regarding Proposed Changes to USP General Chapter <795> Nonsterile Preparations 2018 Draft

Dear USP Compounding Committee:

The California Veterinary Medical Board (Board) would like to thank Dr. Gigi Davidson and the USP staff for the conference call that Board Member Dr. Richard Sullivan participated in on June 15, 2018, regarding concerns that were expressed by the Board and the California Veterinary Medical Association. It was truly above and beyond on your part and we really appreciate the time that you took out of your busy schedule to put this together.

The Board would just like to follow up with a couple of comments. We understand that your goal and concern is for the safety in the use of nonsterile compounded preparations in both human and animal patients; the Board shares the same concern regarding animal patient safety. However, the Board believes we have many existing built in safeguards that will allow clinicians to provide safe and efficacious preparations while protecting the patient and the consumer.

- Veterinarians can only do simple, basic compounding.
- Compounded preparations are made for immediate use or dispensed for immediate use.
- A veterinarian can only do compounding for their patient(s) that they have established a veterinarian-client-patient-relationship (VCPR); they cannot fill a prescription or sell a preparation to another veterinarian or client in accordance with California law.
- A veterinarian has a close relationship with their patients; follow-up exams are routine to evaluate the progress of the treatment including blood tests to evaluate progress and therapeutic blood levels when applicable (i.e. Potassium bromide blood levels).
- If a patient has an adverse reaction, the client typically notifies the veterinarian immediately; this is required to be documented in the medical record.

- If the client is upset or has any issue with medical outcome(s), they may file a complaint with the Board and the veterinarian will have to document why they used the compounded preparation and the reference source for its use, even if the complaint has nothing to do with the compounded preparation. In other words, the veterinarian cannot just make up and randomly use a compounded preparation, they must have a published source for its use or the formula must be recommended from a specialist. Treatment must accord with the standard of practice in the state.
- Much of time, compounded preparations are made from sterile IV medications that are combined and used as a topical preparation as in treating a resistant ear infection.
- In certain minor species such as birds and reptiles, there is no other choice than to do simple compounding to establish a safe dose.
- Without the immediate availability of simple nonsterile compounded preparations, the health of the patient is at risk especially in those patients that instinctually hide their symptoms. Whereas humans are taught to get medical help as soon as they notice symptoms, animals by instinct hide their symptoms because it attracts predators.

Again, thank you for all of the important work that you are doing and together the Board believes we can have guidelines that provide for safe and efficacious use of nonsterile compounded preparations for our animal patients.

Cheryl Waterhouse, DVM, President
Veterinary Medical Board

Richard J Sullivan, DVM, Vice-President
Veterinary Medical Board

Cc: Ashley Morgan, DVM, Director of State Advocacy, AVMA
Kent McClure, DVM, JD, Chief Government Relations Officer, AVMA
Valerie Fenstermaker, California Veterinary Medical Association



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June 18, 2018

USP–U.S.
12601 Twinbrook Parkway
Rockville, MD 20852-1790, USA

**RE: California Veterinary Medical Association Comments on USP General Chapter <795>
Pharmaceutical Compounding – Nonsterile Preparations 2018 Draft**

Dear USP Compounding Committee:

The California Veterinary Medical Association is providing feedback on the USP 795 Non-Sterile Compounding proposed chapter revision. This document is attempting to provide clarity and guidance for both compounding pharmacies and clinical health care practices. These are two very different industries and, at least from the veterinary perspective, the proposal to create a singular guidance for both is problematic.

Veterinary practices differ greatly from compounding pharmacies.

Compounding pharmacies have a specific focus on compounding drugs for distribution. Staff may be trained and dedicated solely to compounding, building construction is intended for this singular purpose, and the business practices center around compounding.

Veterinary facilities are diverse because they must accommodate many different facets of medical practice. It is common for veterinary practices to provide medical treatment for multiple species of patients and to provide emergency/critical care, in-patient boarding, surgery, radiology, dentistry, and several other medical disciplines all under one roof. Practices are therefore constructed to accommodate a wide variety of services.

Veterinary practices can be large, multi-doctor referral centers, corporate owned entities, single-practitioner small businesses, and everything in between. Veterinary medicine is also practiced in the field (in mobile units/house call practices/in a range setting) without a traditional brick and mortar building. Examples include food animal practice which takes place on dairies or in other animal production units, equine practice which occurs in boarding facilities or on a race track, zoo medicine, aquatic medicine, small animal house call practice, mobile surgery clinics, and shelter medicine, among others. Medical insurance is not a significant factor in veterinary health care, therefore most animal owners are paying out of pocket for their pet's veterinary care and medications. This results in a constant push in veterinary practice to keep costs low for both services and medications. Many pet owners cannot afford high prices for veterinary care.

Because veterinary practices differ so greatly from compounding pharmacies, and because veterinarians must retain the ability to perform at least some forms of compounding for patients, California law (Business and Professions Code Section 4826.5) allows the California Veterinary Medical Board (VMB) to promulgate regulations specific to veterinarians compounding drugs for their patients. These regulations do not increase the scope of practice of what veterinarians do. Rather, they create a minimum standard for veterinarians in order to provide important medications to their animal patients.

The VMB worked in consultation with the California Board of Pharmacy over the past three years and drafted veterinarian compounding regulations that are now in the final stage of the rule making process.

The California regulations are based on the 2017 USP 795 standards in which basic categories of compounding (simple, moderate, complex) are defined. The California regulations are based on the concept that the vast majority of compounding that takes place in veterinary practices is simple compounding and that the compounds being prepared are for use in patients on an immediate or near-immediate basis and are not intended for broad distribution or resale to other practices or the public. The current draft of USP 795 proposes to eliminate these compounding categories. This is problematic since California state regulations are based on these categories which accurately reflect veterinary compounding.

The proposed USP 795 introduction states that it describes minimum standards. This presents concern since regulatory inspectors may utilize this chapter in the future from a standpoint of enforcement.

While the proposed USP 795 document indicates in the Scope section that it applies to veterinarians (veterinary practices), as one progresses through the document, it seems apparent that the author was thinking primarily about compounding pharmacy facilities (which exclusively compound, store, package and ship drugs) rather than dispensers that may be performing some degree of compounding.

It is also helpful to recognize that Occupational Safety and Health (OSHA) regulations supplement some of the stated guidance regarding personnel training, safe practices, facilities, personal protective equipment, hygiene, and documentation/recordkeeping.

Specific discussion points regarding the draft:

Proposed language	Comments
Throughout the document there is a reference to a “designated compounding area.” (Lines 129, 350)	Veterinary practices utilize areas for several diverse purposes and most do not have the space to devote <u>solely</u> to compounding. Also, field practitioners will not have access to a designated compounding area.
In section 1.1, under “Affected Personnel and Settings” it states, “Personnel engaged in the compounding of CNSPs must also comply with applicable laws and regulations of the regulatory jurisdiction.” (Lines 39-40)	The California regulations differ greatly from this version of USP 795. The regulations were based on the 2017 version of USP 795. In particular, they rely heavily on the categories of compounding (simple, moderate, and complex) and specify clearly what would be required of a veterinarian compounding under each. Since the current draft has eliminated those categories, California state law would be inconsistent with USP which would result in

	<p>confusion amongst practitioners. Of note- the average regulation takes 3 years to go into effect in California; thus, a change will not be easily or quickly instituted.</p>
<p>In section 2, the draft guidance states, “All personnel involved in the preparation and handling of CNSPs must be trained, must demonstrate competency, and must undergo annual refresher training.” (Lines 64-66)</p>	<p>Most training in veterinary practices is ongoing and informal. Annual refresher training would be challenging in a veterinary practice if it was required to be in-house or on-the-job, particularly for a sole veterinary practitioner because there is nobody to provide the training. This type of training course is not currently available at veterinary continuing education conferences.</p>
<p>In section 2, it states, “Before independently beginning to prepare CNSPs, personnel must complete training and be able to demonstrate proficiency in the theoretical principles and hands-on skills of nonsterile manipulations for the type of compounding they will be performing. (Lines 79-82)</p> <p>Proficiency must be demonstrated in at least the following core competencies:</p> <ul style="list-style-type: none"> • Hand hygiene • Garbing • Cleaning and sanitizing • Component selection, handling and transport • Performing calculations • Measuring and mixing • Use of equipment • Documentation <p>(Lines 82-92)</p>	<p>In relation to the training for personnel, it may be interpreted that in order for a person to “demonstrate proficiency in the theoretical principles and hands-on skills”, that he or she would need to pass a test. There are questions about who would formulate this test and who would verify that the test adequately covers needed material.</p> <p>From the perspective of a veterinary practitioner who is performing simple compounding, some of these requirements do not seem reasonable- such as some of the requirements set forth in the hand hygiene and garbing sections.</p>
<p>Section 3 then goes into further detail on the specific requirements for each of these topics. (Lines 118-163)</p>	<p>The removal of personal outerwear when mixing a compound will be problematic for several veterinary practice types. For instance, it is not reasonable for an equine practitioner mixing up a hoof remedy using iodine on the tailgate of a truck in freezing temperatures to remove his or her jacket.</p> <p>While the intent behind “washing hands and forearms up to the elbows for 30 seconds” is good, it may not be practical for situations such as the one stated above.</p>

<p>In section 4, the draft states, “Compounding facilities must have a space that is specifically designated for compounding. Areas related to nonsterile compounding must be separated from areas not directly related to compounding... (Lines 166-168)</p> <p>Compounding areas used to compound hazardous CNSPs must not be used for compounding nonhazardous CNSPs... (Lines 172-173)</p> <p>Purified Water should be used for rinsing equipment and utensils...” (Line 195)</p>	<p>For a facility that is dedicated exclusively for compounding, these requirements may be attainable, but for most veterinary practices, they are unattainable for the type of compounding that takes place. Additionally, many veterinary facilities have only one veterinarian with limited space.</p> <p>Practices may have an area where compounding occurs, but it will not be specifically designed for compounding and nor will it be exclusive to compounding. Further, it is likely that hazardous drugs would be compounded in the same area where non-hazardous drugs are compounded. With proper cleaning/disinfecting protocols, a compounding area should be able to be used for both types of compounding.</p> <p>Purified water may not be needed for simple compounding purposes in veterinary practices. Clean water is readily available and would be sufficient in many instances.</p>
<p>In section 4, (Lines 187-188), and in Section 5, Table 1 (Line 215), it indicates that ceilings must be cleaned every 3 months.</p>	<p>Construction of veterinary practices does not take into account routine ceiling cleaning and therefore materials are unlikely to be suitable for routine disinfection.</p>
<p>Section 6.1 states, “Any weighing, measuring, or other manipulation of an active pharmaceutical ingredient (API) or added substance in powder form that could generate airborne contamination from drug particles must occur inside a containment device such as a containment ventilated enclosure (CVE) (i.e., powder containment hood). (Lines 232-236)</p>	<p>Several powders are utilized in veterinary practice. For instance, phenylbutazone is a common non-steroidal anti-inflammatory drug used in equine medicine. It is often put into a syringe, mixed with water and then orally dosed to the horse. Incorporating a CVE into a practice in order to give a horse a gram of bute powder is unrealistic for the veterinary profession.</p> <p>There are more examples of powders used in veterinary practice at the end of this document.</p>
<p>Section 6.2 includes a section regarding the requirement for a spill kit. Specifically, it states, “The facility must have a spill kit in the designated compounding area. The condition and expiration date of the chemical spill kit should be verified annually and replaced as necessary. The capacity of the spill kit should be affixed to the packaging of the spill kit if not readily visible on the manufacturer’s label.” (Lines 350-354)</p>	<p>While this makes sense for hazardous chemicals, veterinarians compound non-hazardous chemicals far more often. Having to maintain a kit, have it verified annually and replaced seems inapplicable if the components used to create the compound are themselves, nonhazardous.</p>

Section 7.2 outlines requirements for the master formulation record. (Lines 385-393)	While similar, the California regulations set forth a simplified version of these requirements.
Section 7.3 outlines requirements for compounding records. (Lines 395-408)	While similar, the California regulations set forth a simplified version of these requirements.
Section 9 lists what components, at a minimum, must be on a compounded product label. (Lines 435-468)	These requirements are in conflict with existing California regulations [CCR 16, Section 2032.32 (b)] which do not currently require lot number, storage conditions, dosage form, indication that the preparation is compounded, special handling instructions, or warning statements. Because veterinary practices have software systems and labeling equipment specifically designed to meet the state legal requirements, these additional requirements would be costly, labor intensive, and time intensive to implement.
Section 10 provides detailed guidance on Beyond Use Dates. (Lines 470-589)	Table 3 in Section 10.3 differs significantly from what the California regulations allow.
Section 12.3 states, “The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable. All temperature monitoring equipment must be calibrated or verified for accuracy at least every 12 months or as recommended by the manufacturer.” (Lines 642-646)	For the type and scope of compounding that veterinarians perform, this may be unnecessary.
Section 13 states, “Compounding facilities must develop and implement SOPs for complaint receipt, acknowledgment, and handling. Complaints may include concerns or reports on the quality and labeling of, or possible adverse reactions to, a specific CNSP.” (Lines 666-669)	Veterinary premises are registered with the VMB. As an affiliate of the California Department of Consumer Affairs, the VMB receives and investigates consumer complaints. The VMB works closely with the California Board of Pharmacy on relevant cases. In the event that a client does complain directly to the veterinarian, the California regulations indicate that the complaint and any corrective measures to address it shall be documented.
Section 14 states, “Documentation must comply with all applicable laws and regulations of the regulatory jurisdiction”. (Lines 720-721)	The documentation requirements in section 14 are far more stringent than what California law requires. In contrast to the USP draft, California law does not require: personnel competency assessment, equipment records,

	receipt of components, compounding records, or release testing. This will create confuse among veterinarians.
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The following are examples of non-sterile compounding in veterinary practice:

- Veterinarians need to compound potassium bromide for seizures in dogs. They primarily use phenobarbital for seizures; however, in some cases it does not yield the needed results and in other cases may not be an option because of existing liver disease. Dr. Wayne Berry, former professor of neurology at UC Davis who now practices in Irvine, developed directions to obtain and use a bulk form of potassium bromide. It is compounded by weighing 50 grams of potassium bromide and mixing it with 200 ml. of distilled water to give 250 mg/ml concentration of the medication. Veterinarians calculate the amount of this solution to give to the patient at a loading dose of 350 mg/kg divided and given every 6 hrs. the first day and then 10 mg/kg given twice daily as a maintenance dosage. After two to three weeks of treatment, they obtain a blood sample to determine if there is a therapeutic level of the medication. With this formula, veterinarians are able to safely and effectively treat a 5 lb. Chihuahua or a 120 lb. Rottweiler. Potassium bromide is the example quoted in the USP <795> report as an example of "Simple Compounding - Potassium Bromide Oral Solution, Veterinary."
- Resistant ear infection is another commonly encountered condition for which veterinarians will compound a non-sterile medication in-house. Veterinarians obtain culture samples of the external ear canal and find out what medication or combination of medications will be effective in treating the infection. Veterinary dermatologists provide examples for veterinarians of combinations of injectable antibiotics and antifungal (for yeast infections) medication to mix in saline for a topical ear canal treatment. This type of immediate use treatment has been occurring safely and effectively for years.
- Companion animals (dogs and cats) need compounded pain medications (1/2 strength) and need liquids (kittens and puppies) in place of tablets. Such medications are most effectively compounded in house since doing so circumvents the inevitable delay in treatment that would otherwise occur if they were ordered and obtained from a compounding pharmacy.
- Exotic and zoo veterinarians rely largely on compounded medications because no FDA approved products are available or in the strength needed or in a usable formulation – liquids, etc. and because most compounding pharmacies will not offer the products that they need.
- In equine practice, owners often must provide ongoing nursing care to their horses because equine hospitals are rare, most owners will not transport their horse off the farm for care, and it is impractical and cost prohibitive for a veterinarian to visit a farm daily to provide basic nursing care. Because of the fractious nature of wounded horses, owners often times will have a limited window of opportunity to clean and dress wounds. Veterinarians will often combine topical antibiotic ointment with wound-safe fly repellent ointment into one to avoid horse owners having to apply two different medications to a wound (since they may only get one chance).

Based on a comprehensive review of the proposed USP 795 chapter, and given the differences between human and veterinary compounding, it does not seem feasible to address the minimum standards to be followed by both compounding pharmacists and veterinarians in the same chapter.

Veterinarians need to be able to perform simple compounding of medications for immediate or near immediate use in their practices in order to provide timely patient care. Veterinarians treat multiple species, with wide variations in weight, physiology and health status and cannot anticipate what type of patient they will treat each day. The ability to compound custom medications in-house for emerging situations is pivotal to providing patients with the care they need, especially since many animals do not display signs of illness and often are in serious condition when they are examined. Relying solely on compounding pharmacies to provide medications can cause a treatment delay during situations in which mere hours can make the difference between life and death. Veterinarians also need to be able to dispense a medication compounded in-house for a client to take home to avoid lapses in animal patients receiving medication. Unlike dispensation of a medication from a compounding pharmacy, veterinarians only dispense medications for their own active cases and not for patients from other prescribers. When a veterinarian dispenses a medication, it is done along with active ongoing patient and client communication.

The following are possible solutions that could clarify the issues outlined in this letter.

1. A statement similar to the one included in the introduction of the USP 797 could be added to the introduction of the proposed USP 795 chapter. It could clarify that the standards set forth do not apply to a veterinary clinical practice by stating, "The standards in this chapter do not pertain to the administration or dispensation of CNSPs to patients in a veterinary practice setting". This would address the need for veterinary practices to be able to compound medications and send them home for purposes of patient care and case management.
2. The proposed USP 795 chapter could include a statement in the introduction indicating that the chapter is not intended to supersede any state laws regarding compounding in veterinary practices. This will reduce confusion for veterinarians and enforcement agencies in the future.
3. The proposed USP 795 chapter could exclude veterinarians and veterinary practices and a separate chapter could be written pertaining exclusively to compounding in veterinary practices. If this option is pursued, including veterinary practitioners from several areas of practice (e.g. exotics, equine, zoo med, etc.) should be strongly considered when formulating a veterinary specific chapter.

Thank you for your consideration of our concerns.

Sincerely,



Valerie Fenstermaker
Executive Director



July 31, 2018

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Representative:

On behalf of the American Veterinary Medical Association (AVMA) and our member veterinarians, we appreciate the opportunity to submit comments on United States Pharmacopeia (USP) General Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations. The AVMA is the nation's leading representative of the veterinary profession and speaks on behalf of more than 91,000 member-veterinarians across the United States who care passionately about protecting animal health, animal welfare, and human health. Informed by our members' scientific knowledge, training, and practical experience, we advocate for policies that support our patients and their owners, help protect public health, advance the practice of veterinary medicine, and promote the critical work of veterinarians nationwide.

The AVMA recognizes the USP as an industry leader in the ongoing development and review of standards on best practice for pharmaceutical formulation. The establishment of such standards leads to higher consistency amongst criteria of quality, safety, and efficacy so that, regardless of geographic region, similar medications are available to all veterinary patients.¹ At the same time, USP GC <795> is intended to apply to all who prepare compounded nonsterile preparations (CNSPs). This includes licensed pharmacies that compound medications on a large scale for broad distribution, as well as licensed veterinarians who prepare medications for their patients. Any revisions to USP GC <795> must take in to account clear differences between these types of compounding activities and the facilities in which they occur.

Veterinarians use CNSPs to treat a multitude of species, which vary in physiology, anatomy, and weight. The CNSPs they use may be obtained from a licensed pharmacy or prepared by the veterinarian for use in their patients on an immediate or short-term basis. Most compounding that takes place in veterinary practices corresponds to what USP GC <795> currently classifies as simple compounding. Current protocols allow veterinarians to modify a product to meet their patient's special therapeutic needs, while adhering to USP standards. The proposed revisions to USP GC <795>, which include eliminating the classification of simple compounding, will create challenges for veterinarians because of their incongruence with veterinary practice.

The environments within which veterinarians practice are diverse. Most companion animal veterinarians practice within a traditional clinical setting where patients are examined in an enclosed indoor space, and the environment and sanitary practices may be similar to those encountered in a human hospital. Companion animal practitioners who practice from a mobile van or trailer may also enjoy some of these same amenities, albeit in a smaller space. In contrast, if a mobile companion animal practice is operated out of a personal vehicle (e.g.,

house call practices providing palliative care), then the working environment becomes the vehicle and the client's home. Equine veterinarians often conduct much of their practice from a vehicle, at the racetrack or in a stable. Livestock practitioners, such as those working on dairy farms or with beef producers on a cattle ranch, may find themselves practicing in pastures or fields. For zoo and wildlife veterinarians working conditions may be even more varied and unpredictable. Modifying the practice environment in these latter situations to meet complicated environmental and sanitary requirements is impractical and is not always needed to provide quality patient care (Section 4: Buildings and Facilities, Lines 167-196; Section 5: Cleaning and Sanitizing, Table 1).

Variations in practice settings mean that expectations and opportunities for addressing professional cleanliness will differ between traditional indoor clinics and equine or livestock practices (Section 3: Personal Hygiene and Garbing). For instance, a companion animal practitioner will typically maintain a clean lab coat and will wash his or her hands according to occupational safety and public health guidelines between patients.² However, it may be impractical for a veterinarian practicing outside in a cold climate to remove winter gear to wash their hands up to their elbows for thirty seconds between multiple patients without putting themselves at risk of extended exposure to freezing conditions (Lines 132-133 and Box 3-1).

While applying certain safety measures, such as the use of containment-ventilated enclosures (Section 6: Equipment and Components, Line 232-236), may be possible in a companion animal specialty practice because that practice is housed in a purpose-constructed building, opportunities to access and use such equipment generally do not exist in primary care companion animal practices or on farms visited by equine or livestock practitioners. Furthermore, space constraints in many veterinary clinics and mobile units require most workspaces to be multifunctional. Activities performed infrequently often do not justify establishing a designated space that cannot be used for other purposes (Section 4: Building and Facilities, Lines 166-173).

While the training protocols proposed (Section 1:1 Scope, Affected Personnel and Settings; Section 2 Personnel Qualifications) would serve as valuable resources for practitioners preparing CNSPs, we have concerns with the requirement that adequate training must include demonstration of proficiency in the core competencies listed, because it is unclear who has authority to determine whether the protocols created by designated individuals meet the criteria of the USP and if perceived gaps in training may be grounds for reprimand.

The AVMA supports continued development of standards to ensure that the highest quality medications are available for veterinarians' patients. Such standards serve patients and practitioners best when they practically and appropriately apply to the vocations for which they are intended. After reviewing the proposed revisions and attempting to reconcile them in the context of inherent differences that exist between veterinary practices and compounding pharmacies, we ask that USP:

- (1) Retain, for veterinary practice, the current USP GC <795> category of simple compounding. This will enable veterinary practitioners to continue to perform basic, simple compounding for their patients; or

- (2) Change the proposed revision to USP GC <795> to remove veterinary practitioners engaged in simple compounding, as defined in current USP GC <795>, from the scope of the updated document; or
- (3) Further collaborate with the veterinary community to better understand and address the needs of veterinarians and veterinary patients as each of the sections of the proposed revised chapter are edited.

Thank you again for the opportunity to provide feedback on the proposed revisions. We appreciate your consideration of our concerns and requests and look forward to continued collaboration with USP. If you have questions or would like more information, please contact Dr. Dharati Szymanski, Assistant Director, Division of Animal and Public Health, at (847) 285-6742 or via e-mail to dszymanski@avma.org.

Sincerely,

A handwritten signature in black ink that reads "Janet D. Donlin DVM, CAE". The signature is written in a cursive, flowing style.

Janet D. Donlin DVM, CAE
Executive Vice President and Chief Executive Officer

DS/AM/BS/GCG/KM

REFERENCES

1. American Veterinary Medical Association (AVMA) Task Force on Veterinary Compounding Legislation. 2016. Legislative Proposal Related to Animal Drug Compounding. Presented at AVMA Board of Directors Meeting on May 18, 2016, Schaumburg, IL.
2. Centers for Disease Control and Prevention (2007). *Handwashing: Clean Hands Save Lives. When and How to Wash Your Hands*. Retrieved from <https://www.cdc.gov/handwashing/when-how-handwashing.html>.

The AVMA's Comments Are Endorsed by the Following Organizations:

- Connecticut Veterinary Medical Association
- Illinois State Veterinary Medical Association
- Kentucky Veterinary Medical Association
- Massachusetts Veterinary Medical Association
- Minnesota Veterinary Medical Association
- Missouri Veterinary Medical Association
- Montana Veterinary Medical Association
- Nebraska Veterinary Medical Association
- New Mexico Veterinary Medical Association
- New York State Veterinary Medical Society
- North Carolina Veterinary Medical Association

- Oklahoma Veterinary Medical Association
 - Oregon Veterinary Medical Association
 - Puerto Rico Veterinary Medical Association
 - Rhode Island Veterinary Medical Association
 - South Carolina Association of Veterinarians
 - Virginia Veterinary Medical Association
 - Washington State Veterinary Medical Association
 - Wisconsin Veterinary Medical Association
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- American Association of Bovine Practitioners
 - American Association of Feline Practitioners
 - American Association of Industry Veterinarians
 - American Association of Small Ruminant Practitioners
 - American Association of Zoo Veterinarians
 - American College of Veterinary Dermatology
 - American Society of Laboratory Animal Practitioners
 - National Association of Federal Veterinarians