Section	Requestor	Summary of Request	Background Information Provided Staff
1735	• Road Runner	1735 far exceeds USP in a number of areas	As part of the development of the board's regulations, consideration was given to USP requirements as part of the foundation for the regulations. USP is a scientific nonprofit organization that sets standards to the identity, strength, quality and purity for specific items, including medicines. The USP-NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Specific to compounded preparations, USP provides both general chapters and monographs. There are several relevant chapters used as reference when promulgating the current version of the regulations.
1735	Board staff	Expand the definition to include that combining ingredients from a manufacturer's kit does not constitute compounding.	Some FDA manufacturers sell compounding kits for oral and topical drug preparations, for example prescription mouthwash. These kits include the ingredients and compounding instructions. The kits are issued a national drug code (NDC) by the FDA. The Inclusion of a firm or its products in the NDC directory does not denote approval by the FDA of the firm or any of its marketed products, nor is it a determination that a product is a drug as defined by the Federal Food, Drug and Cosmetic Act.
1735.1 (l)	• CPhA • IACP	Amend the definition of "daily" to specify that electronic monitoring of temperatures is allowable.	Section 1735.1 includes definitions for various words and phrases that are then referenced throughout the remainder of the compounding regulations to ensure the board and its regulated public have a common understanding of terms used.

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Section	Requestor	Summary of Request	Background Information Provided Staff
1735.1(n)	• CPhA • IACP	Amend the definition of "dosage unit" to beyond one administration and allow for one "dosage unit" to be one prescription.	Aside from the definition, the term "dosage unit" is referenced in the definition of a "non-sterile-to-sterile batch" [1735.1(v)] The definition of "non-sterile-to-sterile batch" then determines several other requirements including when end product testing should occur and the quarantining of such products until the end product testing confirms sterility and acceptable levels of pyrogens. Non-sterile-to-sterile compounding is inherently the most risky form of compounding from a patient safety perspective.
1735.1(r)	• Kaiser • Rick Rhoads	Update the definition of hazardous to mirror USP < 800> by July 1, 2018	USP <800> was published on February 1, 2016 in the First Supplement to USP 39-NF 34. The USP Compounding Expert Committee approved a delayed official implementation date of July 1, 2018 to allow entities additional time to implement the standard. This chapter is designed to protect personnel and the environment when handling hazardous drugs. The definition of hazardous drug in USP <800> is any drug identified by at least one of the following six criteria: • Carcinogenicity • Teratogenicity or developmental toxicity • Reproductive toxicity in humans • Organ toxicity at low doses in humans or animals • Genotoxicity • New drugs that mimic existing hazardous drugs in structure or toxicity. The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other hazardous drugs used in healthcare.
1735.1	• CPhA • IACP	Recommend addition of a definition of sterility	According to USP <1211> within the strictest definition of sterility, a specimen would be deemed sterile only when there is complete absence of viable microoraganisms . This chapter notes that the sterility of a lot purported to be sterile

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Section	Requestor	Summary of Request	Background Information Provided Staff
			is therefore defined in probabilistic terms, where the likelihood of a contaminated unit or article is acceptably remote. This chapter along with USP <71> describe the methods by which sterility is tested as well as the various method that can be used for sterilization.
1735.1	Risk Rhoads	Add a definition of "stability"	USP <1191> defines stability as the extent to which a product retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of its manufacture. As part of this chapter, the responsibility of pharmacists as it related to stability are detailed.
1735.2 (a)	Road Runner	Remove the requirement to document prescriber authorization to compound a product. (Although not specifically stated, staff believes this request is specific to CSPs for animals.)	Section 503A, added to the Food, Drug & Cosmetic Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a state licensed pharmacy or federal facility, or by a licensed physician. A compounded drug preparation may be eligible for the exemptions under section 503A of the FD& C act only if it is, among other things, "compounded for an identified patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient." It is customary for a prescriber to notate that a compounded drug preparation is necessary for a patient. When such a notation is not included on a prescription and filling the prescription requires compounding, a pharmacy must contact a prescriber's office to seek approval. When such a

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Section	Requestor	Summary of Request	Background Information Provided Staff
			scenario occurs, the prescriber's approval must be noted on the prescription to memorialize the approval.
1735.2(c)	Wedgewood Village Pharmacy	Expansion of prescriber office use provisions and change in the definition of "reasonable quantity"	Compounding for prescriber office use is currently allowed in board regulation. Because the requirements for compounding a drug preparation are not as extensive as drug products that are manufactured, limitations are generally placed on compounding products for prescriber office use. Further, with the regulation of outsourcing facilities, the need for pharmacies to compound for prescriber office use is reduced because the preparation can be obtained from an appropriately licensed outsourcing facility. Because an entity that only compounds preparations for animal use is not eligible for licensure as an outsourcing facility by the FDA, the question becomes how prescriber's treating animal patients can otherwise take care of their patients. (An entity would be eligible for registration however if even one of the compounding preparations is for human.) Under FDA rules, compounding of animal drugs can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(b)(4) and (5) and 21 CFR part 530. Under federal law a pharmacy may perform anticipatory compounding in "limited quantities before the receipt of a valid prescription order for an individual patient under specific conditions. "
1735.2(d)	Wedgewood Village Pharmacy	Change regulation to indicate that prohibitions to compounding only apply to human drugs	Under the provisions of FD&C Act there are three conditions under which compounding cannot occur including those that are demonstrably difficult to compound or essentially compounds of a commercially available product unless specified conditions are met.

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Section	Requestor	Summary of Request	Background Information Provided Staff
1735.2(i)	Letco Medical	Clarification of the board's interpretation of "identical"	The intent of the board's regulation is to ensure that the same ingredients or components are used. The use of different ingredients or components would require separate consideration when determining the appropriate beyond use dates.
1735.2(i)(1) related to BUDs for nonsterile products	• CPhA • IACP	Clarify the conditions under which a BUD can be extended for a non-sterile compounded preparation.	The beyond use date (BUD) is the date after which a compounded preparation should not be used. It is determined from the date the preparation is compounded. USP <795> notes that compounded preparations are intended for administration immediately for following short-term storage and BUD are established differently than an expiration date of a manufactured drug product. USP notes that a compounder should refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility and degradation and shall use his or her compounding education and experience.
1735.2(1)(2)	• CPhA	Change the requirements to extend a BUD	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs. As part of the standard in USP <797>, truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. The standard notes the preparation specific, experimentally determined stability data evaluation protocols are preferable to published stability information.
1735.2 (i)(3)	• Rick Rhoads • CPhA • Golden Gate VCP	Change the requirements to extend a BUD.	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs. As part of the standard in USP <797>, truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. The standard notes the preparation specific, experimentally determined stability data evaluation protocols are preferable to published

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Section	Requestor	Summary of Request	Background Information Provided Staff
			stability information.
1732.2(i)(3)	• Golden Gate VCP	Request that the board develop a list of drugs that do require the stability indicating assay.	The board is not aware of any such list.
1735.2(i)(5)	• Golden Gate VCP	Concern with the conditions for establishing a shorter BUD	The language establishing the shorter BUD is not new, under the prior regulation, this provision was included in CCR 1735.2(h).
1735.2	• Road Runner	Make stability, container closure, sterility and testing frequency consistent with USP standards.	Standards for the establishment of a BUD are found in USP <795> and USP <797> for CSPs.
1735.2	• Eye Care for Animals	No specific request was provided	
1735.2 (6)	• CPhA • IACP	Recognition that potency over time studies can be used to validate stability of a preparation and assign extended beyond use dates.	According to USP, tests for strength (potency) are designed to determine how much of an active ingredient is in a sample. Stability tests are used to determine an expiration date of a product or a BUD of a preparation. In the paper written by the USP Compounding Expert Committee, it was noted that being able to understand the difference between strength testing versus stability testing is the key to using the proper method to determine strength or stability, noting that determining the strength may or may not be stability indicating. It continues to state that when determining stability, the method must be stability-indicating noting that when using a stability-indicating method, both strength and stability can be determined. USP also included information on this as part of their FAQs, provided below - - **Q. Is there a difference between testing stability with a strength (potency) or a stability-indicating method?**

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Section	Requestor	Summary of Request	Background Information Provided Staff
			A. Yes, a strength (potency over time) test determines the amount of active ingredient in a preparation, however, it may not be able to separate the inactive ingredient from its degradation products and impurities for quantitation depending on the analytical methods used for the test. A stability-indicating method will be able to quantitate the active ingredient and its degradation products or related impurities in the preparation by separating the inactive ingredient from its degradation products and impurities, and to show a change in the concentration of the active ingredient with increasing storage time. A stability-indicating method is used to determine stability of a drug and used to establish the Beyond-Use Date.
1735.6(e)	• Rick Rhoads	Create an exception allowing a pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics	Antineoplastic include preparations such as chemotherapy drugs and are included under the general classification of hazardous drugs and defined by NIOSH. USP <800> provides the standards for the handling of hazardous drugs as defined by NIOSH.
1735.8(c)	• NACDS/CRA	Requests the board develop a list of compounds and dosage forms that would be specifically subject to analytical testing.	The regulation section cited establishes the quality assurance measures.
1751.1(a)(5)	• Board staff • CPhA • International Academy of Compounding Pharmacists • Kaiser	Clarify where the smoke studies must be done and establish a frequency	Smoke studies are used to verify air flow within a specified area. For purposes of this regulation, the smoke study is conducted to verify unidirectional airflow and sweeping action over and away from the compounding area and must be conducted under dynamic conditions.
1751.3	• Kaiser	Clarification on what	USP <797> provides standards for the environmental

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Section	Requestor	Summary of Request	Background Information Provided Staff
		environments require a sampling plan	sampling plan including noting that it should be done based on a risk assessment of the compounding activities performed. The standard indicated that the plan shall include sample location, method of collection, frequency or sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.
1751.3(c)	• Rick Rhoads	Provide detailed description of what the SOPs need to include for sterilization and depyrogenation process	Under the proposed revisions to USP <797>, the standards would provide more specificity to the pharmacy's SOPs regarding the sterilization and depyrogenation process. It is board staff's understating that <797> is still undergoing review and it is expected that another iteration of standards will be released for public comment. We are unaware of an anticipated dated for publication. Currently, USP <1211> provides a general description of the concepts and principles involved in the quality control of articles that must be sterile. Five methods of terminal sterilization, including removal of mircoorganisms by filtration and guidelines for aseptic processing are described in the informational chapter.
1751.4	• Board staff	Clarify that cleaning must be done when hazardous drugs are being compounded as well as what environments must be cleaned.	USP <797> notes that environmental contact is a major source of microbial contamination of compounded sterile preparations (CSP). USP notes that as such "scrupulous attention" to cleaning and disinfecting the sterile compounding area is requirement to minimize this as a source of CSP contamination. USP provides specific areas, surfaces and equipment as well as conditions when cleaning is required. Further, USP <800> establishes the requirements for cleaning environments and equipment where hazardous compounding is performed and build up the requirements of USP <797>. The USP <800> requirements are designed to

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Section	Requestor	Summary of Request	Background Information Provided Staff
			minimize exposure to staff as well as the preparations made. USP <797> Appendix II lists common disinfectants used in health care for inanimate surfaces and noncritical devices. Additionally, USP <1072> provides further information on disinfectants and antispectics.
1751.4(d)	• Kaiser	Add a definition of germicidal to allow the use of a ready-to-use germicidal detergent including sterile water.	Part of the USP <797> is the standard for cleaning and disinfecting the sterile compounding area including the appropriate cleaning agents to be used. As part of USP <800>, standards for cleaning areas where hazardous drugs are prepared are detailed, including the use of germicidal detergent with sterile water.
1751.4(d)(1)	• CPhA • IACP	Clarify that cleaning does not need to happen daily, but rather every day the facility is used to prepare sterile drug products.	As noted above cleaning requirements are detailed in several chapters of USP. USP <797> establishes the minimum frequency of cleaning and disinfecting in compounding areas. Specifically it provides ISO Class 5: At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected. Counters and easily cleanable work surfaces: Daily Floors: Daily Walls: Monthly Ceilings: Monthly Storage shelving: Monthly
1751.4(g)(1)	Rick Rhoads	Create an exception allowing a	Antineoplastic include preparations such as chemotherapy

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Section	Requestor	Summary of Request	Background Information Provided Staff
		pharmacy to perform an assessment to determine alternative containment strategies for hazardous drugs that are not antineoplastics	drugs and are included under the general classification of hazardous drugs and defined by NIOSH. USP <800> provides the standards for the handling of hazardous drugs as defined by NIOSH.
1751.4(k)	CPhA IACP	Remove the minimum room temperature	As part of its standards, USP <797> includes specifications for the compounding facilities, including room temperature. USP determined that compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20 degrees C or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.
1751.4(g)(1)	Kaiser	Recommend adding a requirement for two pairs of standard gloves for all hazardous compounding	USP <800> establishes, as part of the standard, the types of gloves that must be worn when personnel are involved in the compounding of hazardous drugs. The standard requires the compounding of sterile hazardous preparations with two pairs of gloves, including the outer glove that shall be sterile (including the outer glove in the CACI).
1751.6(e)(2)	CPhA IACP	Provide alternative training requirements for staff only involved in the supervision of personnel compounding but not compounding themselves.	USP <797> establishes with great specificity the training requirements someone must meet prior to preparing CSPs.
1751.7(e)(1)	CPhA IACP	Allow for an alternative method of testing as those described in USP <71> to perform end product testing. Also, exempt irrigations from pyrogen testing.	The informational chapter of USP <1223> provides background on the validation of alternative microbiological methods. A pyrogen is defined as any substance that can cause a fever and includes bacterial endotoxins and exotoxins. USP <151> provides background on appropriate pyrogen tests.

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Section	Requestor	Summary of Request	Background Information Provided Staff
1751.8	Eye Care for Animals	No specific request was made	
1751.11	Rick Rhoads	Add provisions to establish requirements for sterilization and depyrogenation	USP <797> is currently undergoing revision. Part of the draft revisions include standards for sterilization and depyrogenation. It is board's staff understating that <797> is still undergoing review and it is expected that another iteration of standards will be released for public comment. We are unaware of an anticipated dated for publication. Currently, USP <1211> provides a general description of the concepts and principles involved in the quality control of articles that must be sterile. Five methods of terminal sterilization, including removal of mircoorganisms by filtration and guidelines for aseptic processing are described in the informational chapter.
BPC 4123	Kaiser	Clarification if the provisions allowing for compounding by another pharmacy under a contract apply to non-sterile hazardous drugs.	B&PC 4123 allows a pharmacy to contract to compound drugs for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy. The contractual arrangement must be reported to the board. The provisions of this section are limited to parenteral. As such non-sterile hazardous drug preparations would not be covered under this provision.

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

CALIFORNIA RETAILERS ASSOCIATION
980 Ninth Street, Suite 2100 Sacramento, CA 95814
(916) 443-1975 calretailers.com

May 31, 2017

Virginia Herold
Executive Officer
Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

RE: Compounding Quality Assurance Requirements under 16 CCR § 1735.8

Dear Ms. Herold,

On behalf of our members operating chain pharmacies in the state of California, the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) want to convey our strong concerns with a provision in the rules under 16 CCR § 1735.8 pertaining to compounding quality assurance requirements. We appreciate the California Board of Pharmacy (Board) considering our comments on this matter.

Specifically, 16 CCR § 1735.8 (c) requires that pharmacies engaged in compounding practices have a quality assurance plan in place that, among other things, "include[s] a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis." In the retail pharmacy setting, the volume of compounding is low and is generally limited to simple and/or moderate non-sterile compounding. The requirement to provide routine testing for simple compounds will lead to various unintended consequences and most importantly will not serve the spirit of the regulation. Analytical testing of simple compounds is not an appropriate measure of potency, but rather more suitable to identify systemic compounding technique errors or equipment flaws only evident in complex compounding. Many retail pharmacies are finding that the cost of complying with this requirement will be exorbitantly high. Without adequate profit to cover the cost of providing the compounding service, many retail pharmacies may eventually stop providing simple and/or moderate non-sterile compounding services. If pharmacies cannot afford to provide this service, it will limit patent access to the important medications.

To maintain patient access to simple and/or moderate non-sterile compounded medications at their local pharmacy, we urge the Board to pursue rulemaking to revise 16 CCR § 1735.8 (c) to specify that the requirement for routine testing and analysis does not apply to simple and/or moderate non-sterile compounded medications. With the majority of retail pharmacy compounding done with commercially available FDA approved ingredients, we believe this change poses little risk to public health and safety. We recommend a more direct approach to this issue and suggest the Board create a list of compounds and dosage forms specifically subject to analytical. This will help ensure that complex compounds that pose the highest risk to public safety are the main focus of such testing.

CRA and NACDS thank the Board for considering our comments on this issue.

Sincerely,

Angie Manetti
California Retailers Association

Mary Staples
National Association of Chain Drug Stores

cc: Amy Guittierez

Eye Care FOR ANIMALS

Frank J. Frassetto III, ACHE, BSHM, CRT
Chief Operating Officer
8145 E. Indian Bend Road, Scottsdale, AZ 85250
480.682.6912 (direct) ~ ff@eyecareforanimals.com

To: California Board of Pharmacy – Executive Committee and Board Members

Re: Compounding Regulations – Effective January 1, 2017.

Members of the Board,

I am writing once again in request of your assistance in modifying the current compounding regulations in place (specifically 1735.2 and 1751.8), which are preventing our patients from receiving appropriate care in a timely manner, (otherwise known as a delay in treatment or in many cases no viable treatment options). Compounders are left with no alternative but to cease and desist shipping medications due to these regulations leaving us with fewer options, in many cases surgical removal of the eye.

I have been physically attending every meeting since my initial correspondence dated April 4, 2017 in preparation for the April 18 meeting. Since that time, you have briefly discussed this issue (3 times in total), but have yet to take any course of action/modification which would allow our Doctors to practice appropriate veterinary medicine within the State of California. Although I fully understand that changing regulations is a "process", I also feel that no course of action is equally as detrimental as the present direction of moving the agenda item from one meeting to the next.

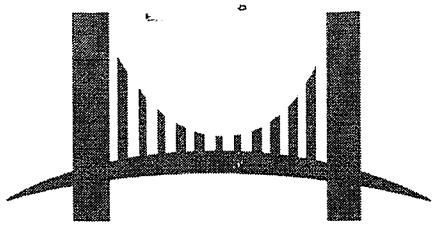
As pointed out during each meeting (by Roadrunner, Diamondback, CVMA, AVMA, and countless others), we are in a holding pattern (by the Board's design), in which no clear cut ruling has been offered which would account for the veterinary side of compounding and/or the ability for my organization to provide necessary care within the confines of your borders. Our California practices are forced to utilize sub-standard treatments for our patient's conditions that would cause legal upheaval should this be occurring in the human healthcare market. There comes a time in which preventing care (as has been done since January 1) can no longer be considered an "oversight" as initially suggested in my correspondence. At this point, we are left with the impression that although you are aware this issue exists, it is not important enough for anyone challenged with protecting the public (or our veterinary patients in this situation), to make a change in their best interests.

I am firmly requesting some sort of amicable remedy be placed into motion during the June 2, 2017 meeting, which would alleviate the continued delays in treatment, forced offerings of sub-standard care, and continued medical complications for our patients.

I will once again be attending the upcoming meeting and welcome any questions posed by the Board which may assist not only our patients, but the entire veterinary community.

Respectfully,

Frank J. Frassetto III, ACHE, BSHM, CRT



GOLDEN GATE VCP

YOUR BRIDGE TO EXCEPTIONAL VETERINARY COMPOUND CARE

05/12/2017

To: California Board of Pharmacy
Executive Officer
Compounding Committee and Full Board Members

Re: Newly Adopted Compounding Regulations

Members of the Enforcement and Compounding Committee,

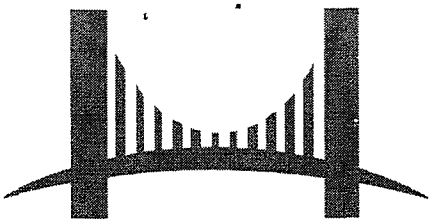
We would first like to commend you for taking on the daunting task of developing and implementing new compounding regulations. Overall a fine job was done and we appreciate that you listened to the compounding community when developing the regulations. We are heartened that you are willing to again listen to the community's feedback.

We are a small independent operation doing business only in the state of California. Our family ownership group runs two licensed compounding pharmacies: Ross Valley Compounding Pharmacy and Golden Gate Veterinary Compounding Pharmacy. Golden Gate Veterinary Compounding is one of the only dedicated veterinary compounding pharmacies in the state. We were at the forefront of PCAB accreditation, originally receiving accreditation in 2010. Since then we have maintained our accredited status adding sterile accreditation in 2014. We feel we are uniquely positioned to provide constructive feedback.

At both Ross Valley and Golden Gate Vet our primary concern is the health and safety of our patients. We strive to provide the highest quality compounds and service for our respective patient populations and can say with confidence that is what we have done over the last several decades of operation. We are USP and ACHC/PCAB compliant pharmacies.

We have two primary areas of concern and they are outlined below.

1525 E. Fransisco Blvd Suite #2B, San Rafael, CA 94901



GOLDEN GATE VCP

YOUR BRIDGE TO EXCEPTIONAL VETERINARY COMPOUND CARE

1) Beyond Use Dating:

1735.2.i.3

"(3) Extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies"

As mentioned by several speakers at the April 18th meeting, the requirement of these tests to extend the beyond use date (BUD) of a non-sterile oral preparation goes above and beyond USP and any other recognized compounding standards. While the BUD dating standards do correspond to USP standards it is the specific requirement of these 3 tests that goes above and beyond the USP requirement. We recommend the regulations be changed to align with the standards set forth in USP 795 which state: "These maximum BUDs are recommended for non-sterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation".

Also, as mentioned by several of the speakers at the April 18th meeting, there is a lack of clarity around *"(C) Stability Studies"*. It appears that many in the compounding community, including our team, have interpreted this to mean that a Stability Indicating Assay test is now required. These are the tests that were mentioned that can run tens of thousands of dollars. Based on the response by the committee, this may or may not be the case, so we would just ask that some clarity be provided as to what testing is going to be required by the Board.

We would also ask that the Board consider the arguments presented at that meeting for the consideration of HPLC Potency Testing as a suitable alternative to a Stability Indicating Assay. If done correctly, a Bracketed Potency over Time Assay will provide more than suitable stability information for the vast majority of compounds. Based on the data we have seen there are only a handful of drugs that are commonly presented as having issues with accurate HPLC testing due to indiscernible degradation peaks – doxycycline comes to mind as one that is commonly referenced. As an alternative to requiring Stability Indicating Assays for all compound BUD extensions, it may be more prudent to identify the few drugs for which this testing would be most appropriate and require the more rigorous testing only for those particular compounds. Ultimately, if Stability Indicating Assays are required the vast majority of independent compounding pharmacies will not be able to afford such testing and will likely begin to go out of business. Those that can afford to test and do move forward with testing will likely be forced to pass those costs along to consumers. Either scenario significantly limits access to these essential medications.

While we agree that in the absence of appropriate data, conservative BUDs should always be implemented for compounded products, the restrictive nature of recent regulatory changes

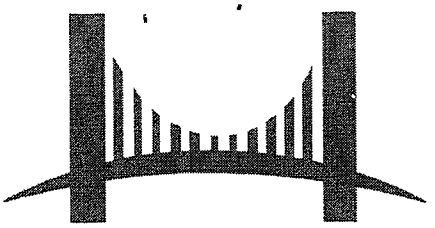
has led to compounding practices that are potentially ineffective and have the potential to cause real harm to patients. Many pharmacies are replacing established, potency study-backed formulas, many of which have years of clinical experience behind them to further justify their use, with new formulas, many of them in oil. On paper, putting a drug in an oil-based suspension seems like a good idea, because the lack of water allows for the pharmacy to assign a 180 day BUD. However, these formulas are even less studied than their aqueous counterparts. How do we know for sure that these new formulations do not have the same, or greater, potential for drug loss or other stability problems? Additionally, the solubility of most drugs is greatly decreased by placing them in an oleaginous environment, where even violent and repeated shaking of the bottle does not suspend the drug well for a long enough period of time to be confident that the correct dose is being administered. These issues, combined with the fact that, for our veterinary patients, the taste and "mouth feel" of oil-based suspensions can cause reactions such as extreme vomiting or aspiration, are why we use oil-based vehicles only as a last resort, where no other vehicle has been shown to be superior.

In many cases, veterinarians have prescribed these newly-formulated oil-based suspensions, and after trying them on the animals, have been forced to consider other dosage forms. For most cases, these liquid formulations were already a second or third-line option for the patient. Many times the patient is unable to safely be given a capsule or tablet, leaving the veterinarian and pet owner with very few options remaining when a viable liquid option is taken off the table.

1735.2.i.4

"(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation."

While we generally agree with this statement, it is very restrictive as currently worded leaving no room for appropriate ingredient substitution or pharmacist's judgment in determining appropriateness of the assigned BUD when forced to substitute. As worded the substitution of one supplier's ingredient for another supplier's similar/equivalent ingredient would not be allowed. General suspending and sweetening agents come to mind. Each distributor/supplier is selling their own version but they are all essentially the same, with minor differences in ingredient make up. It is highly unlikely that substituting one for the other will have a negative impact on stability. It also does not leave room for substitution of equivalent USP/NF ingredients or packaging from different suppliers. We would recommend that the language be softened to allow for substitution of equivalent ingredients if the identical ingredient from the study is not available or stocked.



GOLDEN GATE VCP

YOUR BRIDGE TO EXCEPTIONAL VETERINARY COMPOUND CARE

2) Pharmacist's Judgment:

1735.2.i.5

"(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

Pharmacist's judgment has always been included in previous versions of the regulations allowing for the pharmacist to determine if there is clinical, scientific, or other rationale for extending a BUD. One of the overarching themes that we see in these updated regulations is the removal of the pharmacist's ability to utilize professional judgment in extending a BUD. At our pharmacies, we have always taken the conservative approach, often utilizing a BUD that is shorter than what USP allows. We do not view this as utilization of "professional judgment" but more so our own conservative nature. The utilization of professional judgment was the result of patient conversations, clinical testing results (saliva and blood), potency testing, review of scientific literature, and the application of all that knowledge to determine if maybe a longer BUD was appropriate where standards were more limited. Professional judgment allowed us to determine that while there may not be published data to support, our experience and our knowledge allowed us to make an educated decision to extend a BUD with justification. As written there is no allowable extension of BUD without significant testing and no allowable extension based on pharmacist professional judgment.

Thank you for taking the time to hear our arguments. Again, as we stated, our ultimate concern is with our patient's well-being and we are concerned that without some clarity, these new regulations are going to ultimately limit patient access – both human and veterinary – to life saving compounded medications and lead to decreased compliance for those patients that do opt to try a compounded preparation.

Respectfully,

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