

**AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
STERILE COMPOUNDING COMMITTEE**

2 p.m., April 4, 2016

Hilton Altamonte Springs
350 Northlake Blvd
Altamonte Springs, FL 32701
(407) 830-1985

Committee Members:

Michele Weizer, PharmD, BCPS, Chair
Mark Mikhael, PharmD
Debra Glass, BPharm

Board Counsel:

David Flynn, Assistant Attorney General

Board Staff:

Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. THANK YOU.

Monday, April 4, 2016, 2 p.m.

- 1. Nonresident Pharmacy Registration application and requirements**
- 2. Nonresident Sterile Compounding Permit application and requirements**
- 3. In-state outsourcing facility requirements**
- 4. New business/old business**
- 5. Public Comment**

Participants in this public meeting should be aware that these proceedings are being recorded.

**CHAPTER 64B16-32
NONRESIDENT PHARMACIES**

- 64B16-32.001 Nonresident Pharmacy Permit**
- 64B16-32.003 Nonresident Pharmacy Permit - Mandatory Notification for Change in Location, Change in Pharmacy Name, Change in Corporate Officer and Change in Prescription Department Manager**
- 64B16-32.005 Nonresident Pharmacy Exemption “Isolated Transactions”**
- 64B16-32.007 Nonresident Sterile Compounding Permit for Nonresident Pharmacies.**
- 64B16-32.009 Nonresident Sterile Compounding Permit for Registered Outsourcing Facilities**
- 64B16-32.011 Nonresident Sterile Compounding Permits – Change in Pharmacy Name and Change in Prescription Department Manager**
- 64B16-32.013 Nonresident Sterile Compounding Permits – Change in Location or Change in Ownership**
- 64B16-32.015 Approved Inspection Entities – Nonresident Sterile Compounding Permit for Nonresident Pharmacy**
- 64B16-32.017 Approved Inspection Entities – Nonresident Sterile Compounding Permit for Outsourcing Facilities.**
- 64B16-32.019 Mandatory Inspection for Nonresident Sterile Compounding Permits.**

64B16-32.001 Nonresident Pharmacy Permit.

This permit is required before a pharmacy that is located outside the geographical boundaries of Florida can ship, mail, or deliver, in any manner, a dispensed medicinal drug into Florida.

- (1) This permit does not authorize the nonresident pharmacy to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into Florida.
- (2) An applicant for a nonresident pharmacy permit shall submit an application using Form DH-MQA 1217 (eff. 04/16), "Nonresident Pharmacy Permit Application," which is hereby incorporated by reference and available at [http:// _____](http://_____) or <http://floridapharmacy.gov>. Applicants for a nonresident pharmacy permit must comply with all requirements in section 465.0156, F.S.

Rulemaking Authority ss. 465.005, 465.0156, F.S. Law Implemented ss. 465.0156, 456.065 (3), FS.
History – New _____.

64B16-32.003 Nonresident Pharmacy Permit - Mandatory Notification for Change in Location, Change in Pharmacy Name, Change in Corporate Officer and Change in PDM.

- (1) A change in pharmacy location, pharmacy name, corporate officer, or pharmacist serving as the prescription department manager shall be timely reported to the Board Office within 30 calendar days.
- (2) If there is a change in the name of the pharmacy or the location of the pharmacy, or both, the department shall issue an updated duplicate permit that reflects the change or changes.
- (3) If a duplicate permit is required to be issued pursuant to subsection (2), the permit holder shall pay a \$25.00 duplicate permit fee before the duplicate permit shall be released.
- (4) Any notification required by this section shall be mailed to Florida Board of Pharmacy, Bin C-04, Tallahassee, Florida 32399. If a duplicate permit is required, make the check or money order payable to the Department of Health.

Rulemaking Authority s. 465.005, FS. Law Implemented ss. 465.0156, 456.025(10), FS.

History-New _____.

64B16-32.005

Nonresident Pharmacy Exemption “Isolated Transactions”

- (1) A nonresident pharmacy is exempt from obtaining a nonresident pharmacy permit if the nonresident pharmacy limits its dispensing activity to a one time, per calendar year, isolated transaction.
- (2) An isolated transaction is defined as making a one-time delivery of a dispensed medicinal drug to a single identifiable patient in Florida.
- (3) This exemption is not applicable to the delivery of a dispensed medicinal drug that is a compounded sterile product.

Rulemaking Authority s. 465.0156 (2), FS. Law Implemented s. 465.0156 (2), F.S. History-New

_____.

64B16-32.007**Nonresident Sterile Compounding Permit for Nonresident Pharmacies**

This permit is required before a nonresident pharmacy ships, mails, delivers, or dispenses, in any manner, a patient-specific compounded sterile product into Florida.

- (1) A nonresident pharmacy that obtains a nonresident sterile compounding permit may only ship, mail, deliver, or dispense a patient-specific compounded sterile product into Florida.
- (2) A permit issued pursuant to this section shall be issued with the following conspicuously displayed on the front of the license: Nonresident Sterile Compounding Permit – Patient Specific Prescription Compounding Only.
- (3) A nonresident pharmacy applicant seeking a nonresident sterile compounding permit shall submit an application using Form DH5003-MQA-XXXX (eff. 04/16), “Nonresident Sterile Compounding Permit Application for Nonresident Pharmacies,” which is hereby incorporated by reference. The Form is available at http://_____ or <http://floridaspharmacy.gov>. An applicant for this permit must comply with all provisions of section 465.0158, F.S.

Rulemaking Authority s. 456.0158, FS. Law Implemented ss. 465.0158, 456.065 (3) FS History New _____.

64B5-32.009**Nonresident Sterile Compounding Permit for an Outsourcing Facility.**

This permit is required before an outsourcing facility that is located outside of Florida, ships, mails, delivers, or dispenses, in any manner a compounded sterile product into Florida.

- 1) An outsourcing facility that obtains a nonresident sterile compounding permit may ship, mail, or deliver a sterile compounded product into Florida for office-use and may ship, mail, deliver, or dispense a patient-specific compounded sterile product into Florida. This permit does not authorize the shipping, mailing, delivering, or dispensing of a non-compounded medicinal drug into Florida.
- 2) A permit issued pursuant to this section shall be issued with the following conspicuously displayed on the front of the license: Outsourcing Facility Nonresident Sterile Compounding Permit – Patient Specific Prescription Compounding and Office-Use Compounding.
- 3) An outsourcing facility applicant seeking a nonresident sterile compounding permit shall submit an application using Form DH5004-MQA-XXXX (eff. 04/16), “Nonresident Sterile Compounding Permit Application for Outsourcing Facilities” which is hereby incorporated by reference. This Form is available at <http://www>. or <http://floridapharmacy.gov>.

64B516-32.011

**Nonresident Sterile Compounding Permits – Mandatory
Notification for a Change in Pharmacy Name and Change in
Prescription Department Manager**

- (1) A change in the pharmacy name or a change in the prescription department manager, pharmacist in charge, or the equivalent (i.e., supervising pharmacist) for a nonresident sterile compounding permit for nonresident pharmacies and for nonresident sterile compounding permit for outsourcing facilities shall be timely reported to the board office within 30 calendar days.
- (2) If there is a change in the pharmacy name, the department shall issue an updated duplicate permit that reflects the name change.
- (3) If a duplicate permit is required to be issued pursuant to subsection (2), the permit holder shall pay a \$25.00 duplicate permit fee before the duplicate permit shall be released.
- (4) Any notification required by this section shall be mailed to the Florida Board of Pharmacy, Bin C-04, Tallahassee, Florida 32399. If a duplicate permit is required, make the check or money order payable to the Department of Health.

Rulemaking Authority ss. 465.005, 465.0158(8), FS Law Implemented ss. 465.0158, 456.065(3), FS. History – New _____

64B16-32.013**Nonresident Sterile Compounding Permits – Change in Location or Change in Ownership**

- (1) Change in Location: A change in location for a nonresident sterile compounding permit for nonresident pharmacies and a nonresident sterile compounding permit for outsourcing facilities shall require a new permit. Therefore, in the event of a change of location, the permit holder shall submit an application for a new permit.
- (2) Change of Ownership: A nonresident sterile compounding permit for nonresident pharmacies and a nonresident sterile compounding permit for outsourcing facilities are non-transferable; therefore, if the ownership changes, a new permit shall be required. To determine what constitutes a change of ownership, please review rule 64B16-28.2021.

Rulemaking Authority ss. 465.005, 465.0158(8), FS. Law Implemented s.465.0158, FS.

64B16-28.905 Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities.

All applicants for a nonresident sterile compounding permit must have and present a current and satisfactory inspection report, and all nonresident sterile compounding permit holders seeking biennial renewal of the permit must have and present a current and satisfactory inspection report, as mandated by Section 465.0158, F.S.

(1) **Current and Satisfactory Inspection Report:** An inspection report is current if the inspection report establishes that the inspection took place within the time frames established in Section 465.0158(3)(e), F.S. An inspection report will be deemed satisfactory when the report reflects that the applicant or permit holder compounds all sterile products in compliance with minimum practice and quality standards (minimum standards). The minimum standards are different for those who are only registered as a nonresident pharmacy pursuant to Section 465.0156, F.S., and for those who are registered as an outsourcing facility pursuant to Section 21 U.S.C. 353b.

(2) **Minimum Standards:** Applicants for an initial permit or applicants for biennial renewal that are both a registered nonresident pharmacy and a registered outsourcing facility must meet the minimum standards applicable to a registered outsourcing facility.

(a) **Registered Outsourcing Facility:** The minimum standards for a registered outsourcing facility are the Current Good Manufacturing Practices (cGMP) that are adopted and incorporated by reference in subsection 64B16-27.797(3), F.A.C.

(b) **Registered Nonresident Pharmacies:** The minimum standards for a registered nonresident pharmacy are Chapters 797, 71, 85, and 731 of the United States Pharmacopeia that are adopted and incorporated by reference in subsection 64B16-27.797(1), F.A.C.

(3) **Mandatory State Inspection Report:** The current and satisfactory inspection report must be generated from an inspection that is performed by the regulatory or licensing authority of the state, territory, or district (hereinafter "state") where the applicant is geographically located, unless the applicant meets the acceptable circumstances established herein. The board hereby deems the following as acceptable circumstances for the department's acceptance of a current and satisfactory inspection report performed pursuant to Sections 465.0158(3)(e)1.-3., F.S., in lieu of the state inspection report:

(a) In the event that state or federal law prohibits the submission of the state inspection report;

(b) In the event that the state refuses to perform the inspection or generates an inspection report after completion of the inspection;

(c) In the event that the state is unable to perform an inspection within a reasonable time period from the date requested. Reasonable time period means within 180 days from the date that the applicant requested an inspection be performed. A failure by the applicant to request an inspection within 180 days from the date of permit renewal is deemed not to be an acceptable circumstance;

(d) In the event that the state inspection report documents that the applicant fails to meet the minimum standards adopted in this rule or when the inspection report merely lists an overall pass or fail and does not have the minimum standards enumerated within the inspection report with an appropriate indication of pass, fail, or not applicable, next to each enumerated standard;

(e) In the event the state inspection report would not be admissible in an administrative proceeding pursuant to the provisions of Chapter 120, F.S., or when state or federal inspectors advise they will not testify to the contents, results thereof, or authentication of the state inspection report;

(f) In the event that the applicant is able to submit a current inspection report from the United States Food and Drug Administration that concludes or establishes the applicant is in compliance with cGMP.

(4) **Approved Inspection Entities for Registered Nonresident Pharmacies:** This section is not applicable to inspection reports for registered outsourcing facilities. The board must approve entities for which the department will accept a current and satisfactory inspection report in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory authority of the state, territory, or district where the applicant is located. An entity that wants to be approved as an inspection entity must submit an Approval Request with attached documentation to the board office. The Approval Request, and attached documentation, shall demonstrate compliance with the following requirements:

(a) The entity must be a legally recognizable business entity that possesses a separate existence for tax purposes. An Approval Request must be submitted with business formation documents that establish compliance with this paragraph;

(b) The entity is formed, established, or created to avoid a reoccurring conflict of interest between the entity and those whom the entity will be inspecting. A conflict of interest is a real or seeming incompatibility between the entity's private interests and the entity's duty to conduct an impartial inspection;

(c) The entity will not conduct any inspection in which the entity or an employed inspector of the entity has a conflict of interest;

(d) The entity must have a customized inspection report. The inspection report must enumerate all minimum standards of each of the chapters of the United States Pharmacopeia that are listed in paragraph (2)(b) of this rule. Each enumerated minimum standard must have a place for the inspector to mark compliant or yes; non-compliant, deficient or no; and not applicable. Each enumerated minimum standard must also have room for the inspector to document observations or comments. An Approval Request must be submitted with a copy of the customized inspection report;

(e) The entity must submit any completed inspection report with digital photography capturing each enumerated minimum standard if the enumerated minimum standard is subject to being captured by photography;

(f) With the Approval Request, the entity must submit an inspection history report. The inspection history report must reflect that the applicant has experience performing inspections for compliance with the required minimum standards. To be approved, an entity must have a minimum of 2 years' experience performing inspections and must have performed a minimum of 20 inspections. The required inspection experience may be demonstrated through the experience of the employed inspectors, if the entity has not been in existence for 2 years prior to submitting an Approval Request;

(g) The entity must agree in writing that the entity will not make a recommendation for the granting, denial, or discipline of a permit;

(h) The entity shall have a written policies and procedures manual. The policies and procedures shall at a minimum address the timely completion and proper performance of inspections and must establish protocols and procedures to ensure compliance with this rule. The policy and procedures manual must be submitted with the Approval Request. The policies and procedures shall require the inspections to be unannounced and that the costs of any inspection shall not be based on or differ in the amount based on the results of the inspection;

(i) The entity must agree in writing that it will testify to the contents of the inspection report in any civil, criminal, or administrative proceeding and that the entity agrees that it and any employed inspectors will not request an expert witness fee (Section 92.231, F.S.) for the testimony of the inspector who performed the inspection;

(j) The entity shall maintain all inspection reports and related records for a period of no less than 4 years from the date inspection was concluded;

(k) The entity shall, within 60 days prior to closing, notify the department or the board when it will close or cease performing inspection services and make arrangements with the department for preserving inspections records that are still within the 4 year retention requirement.

(5) Employed Inspectors: The entities' employed inspectors must meet the following criteria:

(a) Any employed inspector must hold an active license to practice pharmacy in any state, territory or district of the United States. Proof of the license shall be submitted with the Approval Request. The employed inspectors may not have any disciplinary history related to the practice of a health profession within 5 years prior to the Approval Request and may have never been disciplined for an offense related to compounding. This provision shall not prohibit the entity from retaining or employing any person that does not hold a pharmacy license for the purposes of assisting the inspectors. For example, it is acceptable to hire a microbiologist or chemist to assist the inspectors in completing the inspection and inspection report;

(b) Any employed inspector must have a minimum of 4 years' experience in the practice of sterile compounding. At least 2 of the 4 years of experience must be obtained through the active practice of compounding sterile products in all risk categories (low, medium, and high risk sterile compounding). The other 2 years may be obtained by one or more of the following: 1) Being employed by a state or federal agency to perform inspections of pharmacies or pharmaceutical manufacturers to determine compliance with minimum sterile compounding standards or current good manufacturing practices standards; 2) Being employed as a full-time instructor at an accredited university for the purpose of instructing students in didactic and clinical instruction on sterile compounding; 3) Being employed to conduct research related to sterile compounding; or 4) Being published in a peer review journal when the article is related to sterile compounding. Three months of credit will be awarded for each published article related to sterile compounding;

(c) At least one of the employed inspectors must have a minimum of 1 year, of the 4 years required, supervisory experience related to the practice of sterile compounding. Supervisory experience is being employed as a supervisor of other pharmacists, not just technicians, in a pharmacy setting that engaged in sterile compounding;

(d) Those employed inspectors which do not have at least 6 months of experience in performing inspections related to sterile compounding must first attend 2 inspections, as a subordinate inspector in training, before being allowed to perform an inspection independently;

(e) The entity must submit a copy of each inspector's employment history and a copy of the each inspector's curriculum vitae (CV) with the Approval Request. The CV must demonstrate that the inspectors are compliant with the experience requirements of this rule;

(f) During the period of employment as an inspector for the entity, the inspectors must have documented training related to sterile compounding and performing sterile compounding inspections. At a minimum, the training must consist of at least 10 clock hours of training annually. The training documentation shall be made available to the board upon written request.

(6) Once an entity is approved by the board, the applicant will be required to maintain compliance with the provisions of this rule or the approval is subject to revocation in compliance with the provisions of Chapter 120, F.S. The department will randomly require documentation of each approved entity to ensure continued compliance with the provision of this rule.

(7) All approved entities shall be listed on the Department's website.

Rulemaking Authority 465.0158 FS. Law Implemented 465.0158 FS. History--New 12-24-15.

Notice of Proposed Rule

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:

64B16-28.802 Special Sterile Compounding Permits

PURPOSE AND EFFECT: The Board proposes the rule amendment to provide a more comprehensive rule for special sterile compounding permits.

SUMMARY: Rule language will be added to provide a more comprehensive explanation of special sterile compounding permits.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.022 FS.

LAW IMPLEMENTED: 465.0196 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allison Dudley, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of Rule 64B16-28.802, F.A.C. follows. See Florida Administrative Code for present text.)

64B16-28.802 Special Sterile Compounding Permits

(1) A Special Sterile Compounding Permit (SSCP) is required before any pharmacy may engage in the preparation of compounded sterile products. For purposes of this rule, an Outsourcing Facility shall be deemed a pharmacy.

(2) An SSCP shall be issued by the department as an additional permit with a separate permit number that differs from the permit number of the pharmacy obtaining the SSCP.

(3) All sterile compounding shall be done in strict compliance with the standards set forth in Rules 64B16-27.700 and 64B16-27.797, F.A.C.

(4) An Outsourcing Facility shall comply with current good manufacturing practices as adopted and incorporated in Rule 64B16-27.797, F.A.C.

(a) If a pharmacy is not registered as an Outsourcing Facility at the time the pharmacy applies for an SSCP, the applicant shall amend the application, within 7 business days, if the pharmacy becomes a registered Outsourcing Facility before the SSCP is issued.

(b) If a pharmacy is issued an SSCP and later becomes registered as an Outsourcing Facility, the pharmacy will not be required to obtain a new or additional SSCP. However, the applicant shall comply with current good manufacturing practices to be eligible to retain the issued SSCP.

(5) The SSCP is not required for a Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope pharmacy if that pharmacy holds no other pharmacy permit and is not registered as an Outsourcing Facility.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History--New 6-18-13, Amended 10-20-13,
_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 11, 2015

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: February 18, 2016

Roach, Emily R

From: zzzz Feedback, MQA_Pharmacy
Sent: Tuesday, December 22, 2015 10:34 AM
To: Roach, Emily R
Cc: Dudley, Allison M
Subject: FW: Animal Drug Compounding
Attachments: FL Board of Pharmacy Letter.pdf

Please respond and copy zzzz box.

From: Brigid Zeller [mailto:bzeller@AHI.ORG]
Sent: Wednesday, December 16, 2015 11:47 AM
To: zzzz Feedback, MQA_Pharmacy <MQA.Pharmacy@flhealth.gov>
Subject: Animal Drug Compounding

Dear Ms. Dudley,

The attached letter is our perspective on the changing regulatory environment for animal drug compounding for your review. Please feel free to contact us if you have any questions.

Best,
Brigid

Brigid Zeller
Manager, Legislative & Public Affairs
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005
202.637.2440
www.ahi.org
www.healthyanimals.org



Healthy
PEOPLE | ANIMALS | PLANET

December 16, 2015

Allison Dudley
Executive Director
Florida Board of Pharmacy
4052 Bald Cypress Way, Bin #C04
Tallahassee, FL 32399-3254

Dear Ms. Dudley,

On the behalf of the Animal Health Institute (AHI), I am writing to share our perspective on the changing regulatory environment for animal drug compounding. AHI is the national trade association representing research-based companies that develop and manufacture medicines for animals.

We are aware that many states have amended or are currently considering amending their statutes and regulations to comply with the Drug Quality Security Act (DQSA) and that these changes, in some cases, have been extended to animal drug compounding. We believe it is very important that as states consider changes to laws for compounding drugs that the state efforts are consistent and reflective of ongoing activity at the federal level.

This past summer, the Food and Drug Administration issued Draft Guidance 230 that specifically describes the Agency's views on animal drugs compounded from bulk drug substances. Both the FDA Guidance and the even more recently issued Government Accountability Office report (Drug Compounding for Animals: FDA Could Improve Oversight with Better Information and Guidance, September, 2015) state that compounding animal drugs from bulk source materials is not permitted by Federal statute

However, both the FDA Guidance and the GAO recognize, and we agree, that some amount of compounding from bulk substances is necessary to meet medical needs. The draft guidance is an attempt at defining the specific instances in which FDA will use discretionary authority to permit this otherwise illegal activity. The guidance is built on the principle that in circumstances where there is less federal regulatory protection, distribution needs to be more limited. Where there are more regulatory protections – as is the case with outsourcing pharmacies – there is more liberality in the distribution. We believe this is a sound principle that serves to protect animal health and guard against small errors becoming large and widespread animal health problems.

We believe that there are medically appropriate instances where limited office stocks of compounded drugs are appropriate in veterinary medicine, and this practice is in accordance with the policy of the American Veterinary Medical Association (AVMA). The policy asserts that “veterinarians should be able to legally maintain sufficient quantities of compounded preparations in their office **for urgent administration needs or emergency situations.**” AVMA Policy on Veterinary Compounding:
<https://www.avma.org/KB/Policies/Pages/Compounding.aspx> (emphasis added).

The AVMA policy further clearly acknowledges that “it is not legal for compounded preparations to be developed in large quantities and sold to third parties (including veterinarians and companies) or wholesalers for resale to individual patients” (see above link). We agree that the AVMA policy does not support large scale compounding for routine office use or dispensing in other than urgent or emergent circumstances.

Manufacturing under the guise of drug compounding remains a significant problem in veterinary medicine. There are compounding pharmacies that manufacture on a large scale from bulk active ingredients for veterinary use and we hope that FDA will quickly finalize their guidance to provide clear enforcement parameters for this activity. Research has shown many of these compounded products to be substandard; they contain too much or too little active ingredient and in many cases, are not stable with shelf lives far shorter than labeled or not labeled at all. Furthermore, there is no mechanism to track non-efficacy and/or adverse event. FDA expresses these concerns in the Draft Guidance, stating that the “unrestricted compounding of animal drugs from bulk drug substances has the potential to compromise food safety, place animals and humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA containing data and information to demonstrate that the product is safe, effective, properly manufactured, and accurately labeled.”

The administration of compounded products that are mass produced with no FDA oversight and outside of the FDA approval process leaves both veterinarians and their clients with no guarantees of the safety and efficacy of the administered product. Any allowance for office use of these products in veterinary patients outside the patient-specific prescriptions should be combined with one or more mechanisms to ensure that the purpose of allowing such use under urgent or emergent circumstances is not circumvented.

Such mechanisms that are currently being used include limiting the volume of the total prescription orders dispensed in a state from an out-of-state pharmacy; requiring compounding for veterinary use to be in compliance with federal law and providing that a pharmacy may only distribute to a veterinarian for dispensing to his or her own companion animal patients where necessary to treat an emergent condition when timely access to a compounding pharmacy is not available. The rarity of these circumstances is demonstrated by AVMA’s recent submission to FDA’s request for comments as FDA establishes a list of compounds that may be manufactured from bulk drug substances by Outsourcing Facilities (under FDA enforcement discretion) for veterinary office stock. After “extensive consideration” the AVMA identified only 14 preparations compounded from bulk drug substances as necessary for in-office use by veterinarians to treat urgent or emergent situations for cats, dog, and horses.

As you review your regulation and policies and consider amendments, we ask that you work to ensure that any action does not inadvertently pave a path for veterinary compounders to manufacture on a large scale under the guise of compounding.

We would also be pleased to provide additional information on this important animal health issue and hope that you reach out to us, and other relevant stakeholders, as you craft news rules, regulations, and/or guidance.

Sincerely,

A handwritten signature in black ink that reads "Alexander S. Mathews". The signature is written in a cursive, flowing style.

Alexander S. Mathews
President and CEO