September 10, 2024

[VIA ELECTRONIC MAIL TO ORAPHARM4_RESPONSES@fda.hhs.gov]

CDR Steven E Porter, Jr
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
ORAPHARM4_RESPONSES@FDA.HHS.GOV

Subject: Authorization to Publish Precision Equine LLC, now known as Wedgewood Pharmacy LLC ("Precision") Response to Untitled Letter dated July 30, 2024 [Reference: CMS 688994]

On behalf of Precision, I authorize the United States Food and Drug Administration ("FDA") to publicly disclose the information described below on FDA's website. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C.§ 331(y)(2), and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing of the information with the public.

Information to be disclosed: Precision's Response to Untitled Letter dated July 30, 2024.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial, financial, or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Precision. My full name, title, address, and telephone number is set out below for verification.

Sincerely,

Shauna Doherty, PharmD
General Manager- Bakersfield
Wedgewood Equine
5301 Young St.
Bakersfield, CA 93311
877.734.3338

CDR Steven E Porter, Jr
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
ORAPHARM3_RESPONSES@FDA.HHS.GOV

Dear Mr. Porter,

This letter is in response to the Untitled Letter dated July 30, 2024, ("Reference case: 688994"). As an introductory comment, Precision Equine LLC, now known as Wedgewood Pharmacy LLC ("Precision"), takes all Form 483 observations seriously and is dedicated to ensuring patients and veterinarians have access to the highest quality compounded medications. We appreciate your review of our responses to the Form 483 observations on October 16, 2023, November 15, 2023, December 15, 2023, January 15, 2024, and February 15, 2024.

Precision is committed to enhancing its quality systems and commonly exceeds applicable standards for compounding pharmacies. As a preliminary matter, though, we believe that FDA's authority to regulate animal compounding is questionable.[1] As the FDA is aware, Precision is a state licensed compounding pharmacy and not an outsourcing facility or FDA registered drug manufacturer. Accordingly, Precision disagrees with FDA's assertion made in several places in the Untitled Letter that it is subject to Current Good Manufacturing Practices ("CGMP") and its labeling fails to bear adequate directions for the intended uses. Precision prepares and labels its compounded medications in accordance with applicable state laws and regulations, and we are unaware of any statutory authority to apply cGMP standards to state regulated pharmacies who compound medication intended for veterinary use.

We question the appropriateness of including discussion items from our inspection meetings regarding compliance with FDA's Guidance for Industry #256 in an Untitled Letter. None of these findings were observations in the FDA 483.[2] Per FDA's Investigations Operations Manual,

---

[1] Unlike Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act ("FFDCA") that provide exemptions for compounded drugs from Section 505 approval requirements, there is no similar Section of the FFDCA which expressly addresses animal drug compounding. Thus, we strongly believe that Congress intended the regulation of animal drug compounding to be left to the states. We note that in a 2011, a federal district court judge rejected FDA's position that compounding animal drugs from bulk is a per se violation of the FD&C Act. While the court's order was subsequently vacated (and the appeal was dismissed) upon agreement by the parties, the decision brings into question FDA's position that "[d]istribution of animal drugs compounded from BDS [bulk drug substances] without an approval or index listing violates the FD&C Act." See United States v. Franck's Lab, Inc., 816 F.Supp.2d 1209 (M.D. Fla. 2011), order vacated, appeal dismissed, 11-15350, 2012 WL 10234948 (11th Cir. Oct. 18, 2012).*But see, e.g., United States v. Kohll's Pharmacy & Homecare Inc.*, W.D. La. No. 2:17-CR-00039, 2017 WL 2951580 (W.D. La. July 6, 2017) (unreported criminal case where the court concluded that drugs compounded for veterinary use are subject to the FD&C Act); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008) (holding that drug products compounded in bulk for animal use by pharmacists and veterinarians were "new animal drugs" that were subject to the FD&C Act's unsafe, adulteration and misbranding requirements, unless these compounded drugs were exempt under the FD&C Act's Animal Medicinal Drug Use Clarification Act (AMDUCA)).

[2] See p.1 of the Untitled Letter "The investigators also discussed the circumstances under which you produce animal drugs from bulk drug substances and distribute them, including drugs for food-producing animals, copies of FDA-approved products, and office stock compounded without patient-specific prescriptions…Although your responses addressed the objectionable practices and conditions related to drug quality described on the FDA Form 483, they did not indicate any changes to the circumstances under which you intend to produce and distribute unapproved new animal drugs from bulk drug substances."

"Discussion Items will not be listed on the form FDA 483, FDA 483a, or FDA 4056, they will be documented in the EIR and may be followed up on at the next inspection."[3] As such, there exists no requirement to respond to discussion items. Additionally, if these undocumented discussion items occurred, they pertain to perceived noncompliance with GFI #256 which "Contains Nonbinding Recommendations."[4] We believe that issuing an advisory action based on perceived noncompliance with nonbinding guidance when no prior written notice was provided to Precision trivializes the effect of Untitled Letters. Nonetheless, while we are aware of no requirement to respond to discussion items, in the spirit of cooperation we will respond to the points raised in the Untitled Letter.

We first address below the issues contained in both the 483 and the Untitled Letter and then address the GFI #256 discussion items as described in the Untitled Letter. We note that quotes from the Untitled Letter are copied in bold below and the text that follows such quote is our response to such text.

1. Drug Quality Violations

"All animal drugs produced from bulk drug substances are subject to the FD&C Act's Current Good Manufacturing Practice (CGMP) requirement, section 501(a)(2)(B), and Page 5 CMS 688994 www.fda.gov our inspection determined that you are not in compliance with that requirement. We noted that your firm sells office stock which potentially exposes large numbers of animals to drugs which do not meet the CGMP quality standard set by the FD&C Act. We further noted that your firm produces copies of FDA-approved products from bulk drug substances but does so without the same CGMP controls which ensure their quality. For example, unlike FDA-approved products, you fail to test the strength/potency of each batch, 4 perform stability testing, 5 and establish, follow and validate all aseptic and sterilization processes to prevent microbial contamination."

As the FDA is aware, Precision is a state licensed compounding pharmacy and not an outsourcing facility or FDA registered drug manufacturer. Accordingly, Precision disagrees with FDA's assertion made in several places in the Untitled Letter that it is subject to Current Good Manufacturing Practices ("CGMP") and its labeling fails to bear adequate directions for the intended uses. Precision prepares and labels its compounded medications in accordance with applicable state laws and regulations, and we are unaware of any statutory authority to apply cGMP standards to state regulated pharmacies who compound medication intended for veterinary use.

As a preliminary matter, we strongly disagree with FDA's assertion that "…[w]hen drugs are compounded for use as office stock, and are therefore readily available for use, the products potentially expose large numbers of animals to drugs." Our extensive experience with both dispensing patient-specific prescriptions and filling office stock orders shows that drugs are ordered by veterinarians to treat individual patients who need such drugs. The fact that some of these drugs are on hand as office stock to treat animals when immediately needed does not increase the number of animals that ultimately need treatment. Our ordering history shows that the typical

---

[3] FDA Investigations Operations Manual, Section 5.5.12.4.

[4] Guidance documents "do not have the force and effect of law." Perez v. Mortgage Bankers Ass'n, 575 U.S. 92, 97 (2015) (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)).

office stock order is less than 10 units thus showing that "large numbers of animals" are not being exposed to drugs that would not otherwise be prescribed for them

Precision generally does not compound copies of approved or indexed products. Consistent with the plain language of GFI #256, Precision has prepared compounded versions of approved or indexed products if there is a difference between the compounded drug and the FDA-approved or indexed drug that will produce a clinical difference in the identified patient as determined by the treating veterinarian. A clinical difference is described as encompassing a wide range of issues encountered in veterinary medicine, including changes in flavoring or dosage form to achieve patient compliance. Precision collects medical rationale as determined by the veterinarian.

As a state licensed pharmacy, we follow USP guidelines and state pharmacy rules. Our potency, sterility programs, and sterile validation processes are in compliance with all applicable standards for a state licensed pharmacy.

"Additionally, unknown yellow stains were observed by the FDA on the HEPA filter inside the ISO 5 laminar air flow hood (LAFH) in the Sterile Non-Hazardous Drug Suite, which is used for producing sterile animal drugs. However, your response does not contain an investigation of the root cause. It is critical to perform comprehensive investigations into product failures, to ensure identity, strength, and quality of drug products before they are dispensed and administered."

We acknowledge the observation and understand the importance of a thorough root cause investigation. In our initial 483 response we committed to enhancing our surveillance of the hoods as well as our investigation process. A root cause analysis was conducted following the Agency's inspection. The investigation determined the most likely cause of the stains was splatter from a filter pressurized by the repeater pump process.

As mentioned in our 483 responses, LAFH 1 was not used after discussing the possible issues during inspection until a full assessment could be made. A qualified third-party certifier, utilizing CETA guidance, conducted a HEPA leak test on LAFH 1 with the discolored HEPA filter on 9/12/23. The HEPA filter passed the leak test showing the filter was not compromised despite the discoloration. The HEPA filter in LAFH 1 was then ultimately replaced on 9/13/2023. As part of the retrospective analysis Precision determined that there were no failed sterility tests of any compounded sterile batches within the assigned beyond use date shelf life compounded within LAFH 1 in the non-hazardous clean room. There have also been no environmental monitoring results exceeding action levels in the non-hazardous clean room or customer complaints of adverse reactions from batched compounded using the equipment identified in the 483 observations.

Additionally, as discussed in our 483 response, Precision has updated SOP 1.030, Deviations-OOS and Corrective and Preventative Action (CAPA) Management, to expand the definition of procedural deviations to include equipment abnormalities utilized in aseptic processing or equipment abnormalities that have the potential of cross-contamination risk. All procedural deviations require a documented investigation. Precision also updated SOPs 1.040, Use and Control of LUMACs, and 4.010, Compounding Equipment, to include reporting instructions of equipment abnormalities to the Facility Supervisor and pharmacist supervisor with specific responsibilities for each. SOP 1.040, Use and Control of LUMACs, also has an increased

frequency of equipment review from annually to monthly. SOPs are effective as of 10/13/23. Staff training was completed 11/15/23. The SOPs referenced were previously provided as part of our 483 response.

2. Assertions Related to Drugs for Food Producing Animals (p. 2-3 of the Untitled Letter)

Use of drugs compounded from BDS to treat food-producing animals and free-ranging wildlife species risks exposing humans to harmful residues in the animals' edible tissues because these drugs have not been reviewed to determine food safety. According to your product labels, compounding log, and prescriptions, you compounded the follow products for use in food-producing animals:

- **Prescription #401717: Dexamethasone Sodium Phosphate in Water, Injectable, 24mg/mL, for use in deer**
- **Prescription #398942: Toltrazuril in Oil 2.2mg/10mL (220mg/mL) Suspension, for use in deer**
- **Prescription no. 399595: Xylazine in Water, injectable, 333 mg/mL, for use in goats. Although prescription 399595 asserts that the goats are non-food producing, it does not provide any further information about the goats or their uses. The label includes a withdrawal time. A withdrawal time is intended to ensure that food products from a treated food-producing animal are safe to enter the food supply by establishing sufficient time from when the animal was last treated with the drug to when the animal is milked or slaughtered for food. Based on the labeled withdrawal time, this prescription appears to be for food-producing animals."**

Precision does not prepare compounded medications for food-producing animals and has a new process to ensure documentation is received from the veterinarian confirming the animal is not intended for the food chain.

- Prescription #401717 was written for a population of deer that are not intended for the food chain. The veterinarian on record was able to confirm this and establish the medical need for this medication to be compounded at a higher concentration for use in dosing via a dart gun. The typical volume for the dart guns is 1ml-2ml requiring a higher concentration of the drug to be compounded to meet the minimal volume requirements of the dart. This is a life-saving medication to treat the symptoms of a viral illness, Epizootic Hemorrhagic Disease (EHD) in deer.

- Prescription #398942 was written for an individual population of Fallow Deer fawns to treat coccidosis. These juvenile animals are strictly kept in the breeding pen and do not enter into the active hunting areas nor would they enter the food chain. There are no commercially available toltrazuril medications and the prescribing veterinarian specifically requested an apple flavored suspension.

- Prescription #399595, was written for an individual herd of Markhor Goats, an exotic species. The veterinarian indicated these animals are non-food producing but out of an abundance of caution we collected the withdrawal time. This medication was to be

administered by dart and is thus needed in a higher concentration than commercially available options. As mentioned above, the average sized dart can hold 1ml-2ml of solution therefore requiring compounding at a higher concentration than is available commercially.

3. **Assertions Related to Copies of Approved or Indexed Products (pp. 3-4 of Untitled Letter)**

"Copies of Approved or Indexed Products
FDA considers an animal drug compounded from a bulk drug substance to be a copy of an FDA approved or indexed product if it has the same active ingredient or active moiety and can be given by the same route of administration ("ROA"). In addition, the FDA considers a combination drug product to be a copy if any of its active ingredients is approved in the same ROA. Compounded copies of approved or indexed drugs are an FDA priority for enforcement because they may expose animals to drugs produced under less quality controls compared to approved/indexed products and reduce incentives for firms to seek approval or indexing of their drugs. You compound copies of approved products, for example:

- **Prescription no. 400961: Azithromycin in Oil, 200 mg/mL Suspension, 2000 mL for 8 horses "in breeding barn"**
    - **Your azithromycin (oral ROA) is a copy of multiple FDA-approved drugs containing azithromycin for oral administration, including suspensions as well as tablets. Among the approved suspensions are NDAs 050693 and 050710, and ANDA 205666. Your records state that patients "would require too many commercial tablets," but do not address why the approved suspensions cannot be used.**

- **Prescription no. 399198: Fenbendazole in Oil 20% Suspension, 2000 mL for horses "in Mare Barn"**

    Your fenbendazole suspension (oral ROA), is a copy of approved orally administered drugs intended for use in horses containing fenbendazole, including an oral suspension, NADA 128-620, an oral paste, NADA 120- 648, and granules for top dressing of feed, NADA 121-473. Your records state that the patient "isn't compliant w/ commercial product. [Too much volume required]" but do not address why the volumes required for all of these approved products would be inappropriate for each of the horses to be treated. For example, NADA 128-620 is a 10% suspension, 1000 mL bottle, and is approved for horses. The labeled dose of this product for horses is 5-10 mg/kg. At the higher end of the dosage range, an average 500 kg horse would require 50 mL of the approved product, which is generally an acceptable amount to administer orally to a horse.

- **Prescription no. 400432: Ivermectin/ Praziquantel in Oil 10mg/45mg Per mL Apple-Flavored Suspension, 600 mL for "6 horses in barn 1"**
    - **Your ivermectin and praziquantel combination (oral ROA) is a copy of approved oral paste products containing both these ingredients, including**

NADA 141-214 and NADA 141-215. In addition, these active ingredients are available separately in approved products, including NADA 134-314 (ivermectin paste) and NADA 111-798 (praziquantel tablets). Your records state that the patients "would require too much volume of commercial products" but do not address why the volumes required would be inappropriate for each of the horses to be treated or whether the approved products could be used separately instead of in combination"

Precision generally does not compound copies of approved or indexed products. Consistent with the plain language of GFI #256, Precision has prepared compounded versions of approved or indexed products if there is a difference between the compounded drug and the FDA-approved or indexed drug that will produce a clinical difference in the identified patient as determined by the treating veterinarian. A clinical difference is described as encompassing a wide range of issues encountered in veterinary medicine, including changes in flavoring or dosage form to achieve patient compliance. Precision collects medical rationale as determined by the veterinarian.

- Prescription #400961:. The rationale received from the veterinarian of "would require too many commercial tablets" we believe is entirely appropriate and consistent with the plain language of GFI #256[5]. Based on the standard dosing for a horse, an average sized equine patient would require 10 of the 500mg tablets, which would be reasonable for a veterinarian to determine as an overly burdensome tablet load. While not required by GFI #256, we do note that the commercially available options of azithromycin are cherry or banana-cherry suspensions, as well as a 250mg and 500mg tablets. The prescription was written for an apple-flavored suspension for ***an equine*** patient to help achieve patient compliance. It is obvious to us that when a veterinarian prescribes a flavored medication that is not an FDA-approved product, the flavoring, in the veterinarians' opinion, is necessary to ensure compliance. Because the veterinarian through his or her VCPR is in the best position to determine what will best provide compliance we do not believe it is appropriate to question their decision. We would not expect FDA to question the medical rationale provided by a veterinarian as they have no history or experience with the individual patient. Veterinarians commonly refer to difficulty with "pilling" to not only describe the literal inability to administer a capsule or tablet but also in reference to difficulties animal patients may experience with any oral administration such as aversion to certain flavors.

- Prescription #399198: The rationale received from the veterinarian was "isn't compliant w/ commercial product. [Too much volume required]". We would not expect FDA to question the medical rationale provided by a veterinarian as they have no history or experience with individual patients. Medication compliance is reliant on several factors including volume of dose given. When considering oral administration to equine patients, compliance is more attainable with a smaller volume as it is easier for the animal to swallow

[5] GFI #256 (p.12) provides that "FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder both documents that the determination was made and contains a medical rationale describing the clinical difference. **We have adequately both documented the veterinarian determination and described the medical rationale and thus complied with the requirements of GFI 256.** The statement in the Untitled Letter that "it is not clear why the patient would be noncompliant with an approved product." directly contradicts this statement in GFI #256 as it questions the veterinarian's determination.

and lowers the chance of the animal spitting it out or causing physical harm to the handler. As the FDA noted the commercial product may require up to "50 mL of the approved product, which is generally an acceptable amount to administer orally to a horse". In this case, the veterinarian stated a smaller volume was required indicating to us that the "generally acceptable" volume was too much for these particular animals or this particular handler. The prescribing veterinarian is in the best position to make that determination.

- Prescription #400432: The rationale received from the veterinarian was "would require too much volume of commercial products". We rely on the veterinarian and their established VCPR to determine the appropriate treatment in selecting a single preparation or combined preparation for a patient. If the veterinarian has determined that a liquid combination product that requires less volume is more appropriate for their patient, then we trust that they are making the right decision for their patient and the patient's handlers. Every horse is different and every handler has a different level of comfortability when it comes to dosing these 1,000-pound animals. We are not in a position to challenge the veterinarian's determination. As previously stated, we would also not expect FDA to question the medical rationale provided by a veterinarian as they have no history or experience with the individual patient or patients. Veterinary medicine is regulated by the State Boards of Veterinary Medicine. By questioning the clinical decisions of the veterinarian, it appears that the FDA is attempting to regulate the practice of veterinary medicine when the ultimate decision on how to treat their patients should be left up to the treating veterinarian.

4. Assertions Related to Office Stock (p. 4-5 of the Untitled Letter)

"Office Stock" refers to compounded drugs ordered by a veterinarian without a patient-specific prescription to keep on hand in the veterinary clinic or office to administer or dispense to patients. When drugs are compounded for use as office stock, and are therefore readily available for use, the products potentially expose large numbers of animals to drugs of unproven safety, effectiveness, and quality. You compound drugs for office stock, for example:

- **Prescription no. I90039584: Praziquantel/ Pyrantel Pamoate/ Fenbendazole in Oil 45.4mg/ 45.4mg/ 50mg Per mL Suspension, 100 mL "to treat worms in equine."**
- **Prescription no. 397623, Xylazine in Water 333 mg/mL Injectable 60 mL for animal identified as "#5212 (Horse)." Although this prescription lists a specific patient, the animal owner and veterinarian are the same individual and the amount dispensed appears to exceed the amount needed to treat a single horse using the labelled directions. At the higher end of the dosage range (1-2 mg/kg), a 500 kg horse would require 5-10 mL of the approved product, or 1.5-3 mL of the compounded product. Thus, it appears this product is intended to be distributed to more than one horse by the veterinarian who ordered it**

As a preliminary matter, we strongly disagree with FDA's assertion that "...[w]hen drugs are compounded for use as office stock, and are therefore readily available for use, the products potentially expose large numbers of animals to drugs." Our extensive experience with both

dispensing patient-specific prescriptions and filling office stock orders shows that drugs are ordered by veterinarians to treat individual patients who need such drugs. The fact that some of these drugs are on hand as office stock to treat animals when immediately needed does not increase the number of animals that ultimately need treatment. Our ordering history shows that the typical office stock order is less than 10 units thus showing that "large numbers of animals" are not being exposed to drugs that would not otherwise be prescribed for them.

- Prescription I90039584: We would like to point out there was a processing error regarding the species for this prescription. It was confirmed verbally with San Joaquin Veterinary Hospital on 9/26/23 this order was to be administered to kittens and puppies for deworming, not equine patients. At the time of FDA's inspection, this compound was on the "Bulk Drug Substances Currently Under Review" List and therefore allowed to be compounded for office use in dogs and cats. It was moved to the "Reviewed and Not Listed" list on 11/20/2023 at which time we ceased compounding for office stock. The staff was retrained on order intake and good documentation practices to ensure they are capturing and documenting the correct species for intended use.

- Prescription #397623: Although the prescription appears to be in excessive quantity for one horse, it is not unreasonable considering the intended usage. This medication is typically used for procedures requiring sedation and would therefore only be administered by a veterinary professional. The prescription was for 2x30ml containers which is not excessive considering the BUD after initially puncturing the vial is 28 days. The DVM may have been concerned about contamination risk after puncturing if there were multiple planned procedures that exceeded the 28-day BUD after puncture. Again, this is a scenario where we would not expect FDA to question a clinical decision by the veterinarian as the Agency has no history or experience with the individual patient.

5. Assertions in Conclusions (pp. 5-7 of the Untitled Letter)

"As described in GFI #256, the FDA has reviewed information concerning specific antidotes, anesthetics, and sedatives for food-producing animals and free ranging wildlife for which the FDA generally intends to exercise enforcement discretion. These drugs are on the List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species. 9 As discussed above, you produce drugs containing dexamethasone sodium phosphate and toltrazuril for use in deer and xylazine for use in goats. The FDA reviewed information on xylazine and did not include it on the list because there are FDA-approved drugs containing the same active ingredient, in the same or similar dosage form, that can be used in an extralabel manner. The FDA has not reviewed dexamethasone sodium phosphate or toltrazuril for use in deer."

As noted in Section 2 above, Precision does not compound drugs for food-producing animals and has enhanced our process to ensure documentation is received from the veterinarian confirming the animal is not intended for the food chain.

"FDA recognizes that there are some circumstances in which the treating veterinarian determines that a particular patient cannot be treated with an FDA-approved product and needs a compounded copy with a specific difference from the FDA-approved drug. GFI-256 recommends that pharmacies obtain a medical rationale from the treating veterinarian that explains how the prescribed compounded product makes a clinical difference for the patient. This statement should explain why the approved drug cannot be used by identifying which characteristics of the approved/indexed drug is unsuitable for the individual patient and how the characteristic has been altered in the prescribed compounded drug so as to create a clinical difference for the individual patient. A general statement of "Patient Noncompliance" does not explain why the approved drug should not be used because it does not identify which characteristic of the approved/indexed drug is unsuitable for the individual patient and how that characteristic has been altered in the prescribed compounded drug so as to create a clinical difference for the individual patient."

While we understand the Agency's goal and intention in requiring identification of "which characteristics of the approved/indexed drug is unsuitable for the individual patient," we disagree that "Patient Noncompliance" is an insufficient description as to why a compounded drug is needed. It is neither reasonable nor practical to gather the level of information expected by the Agency from a non-verbal animal patient. Additionally, we also note that in the plain language of GFI 256 the Agency stated, "FDA does not generally intend to question the veterinarian's determination the patient will not accept the specified dosage form if the prescription is for a different dosage form." In our experience, animals will often stop taking a prescribed medication without an identifiable reason. Animal owners and caretakers often report that an animal was taking a medication easily and then without any explainable reason, began refusing all attempts to medicate. Requiring a veterinarian to determine the exact characteristic leading to the non-compliance will result in significant delays in patient care and cause undue stress on the animal. The end result of these efforts likely leads to the same conclusion: the approved product is not being accepted by the animal patient and a compounded version is needed. Noncompliance with the approved/indexed product is by far the most frequent reason that a veterinarian turns to a compounded preparation, and we rely on the veterinarian and their VCPR to determine the best course of therapy.

As noted above we disagree that the medical rationales provided by veterinarians and documented by Precision are inadequate. GFI #256 (p.12) provides that "FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation." Similarly, we do not think it is appropriate for a pharmacy to question the medical rationale provided by a veterinarian who has a VCPR. Accordingly, we believe that these rationales comply with the requirements of GFI #256.

"We note that you document rationales for using BDS instead of approved products using a table that maps bulk drug substances you use to make various specified dosage forms to justification codes, each of which contains a general description. We are concerned that these rationales do not explain why an FDA-approved/indexed drug cannot be used, particularly when the compounded drug is a copy of more than one FDA approved drug. As examples: the justification "[e]xcipient in approved product affects flavor and/or texture making compound unacceptable" neither specifies the excipient nor explains the specific underlying

problem (bitterness, grainy texture, etc.). You also have several justifications that generally state the conclusion "[i]t is not possible to compound [this dosage form] from [another dosage form]," but do not state the underlying reason. Similarly, the justification "Preparation would require too many tablets/capsules/vials of the approved product," does not explain how many doses of the approved product would be required compared to the compounded product."

The document Precision provided to FDA regarding the reasons why it is not possible or advisable to compound a particular drug from an FDA approved/indexed drug shows our general approach when determining if an FDA-approved/indexed product is reasonable as a starting ingredient. It represents decades of compounding knowledge and professional judgement. While we may not have determined the specific excipient that causes an oral suspension to cake or flocculate, we know that using tablets or capsules as the starting source often leads to this issue resulting in erratic dosing or under/overdosing of the animal patient. When we say that "too many tablets/capsules/vials of the approved product would be needed," we are referring to the production of a final dosage form that will be acceptable to the patient. For example, when making a capsule for a cat we want the capsule size to be as small as possible to ensure successful treatment. Using an approved/indexed tablet or capsule as the starting source regularly results in too large of a capsule to reasonably dose a feline patient. Again, we make the point that determining what a non-verbal animal patient does not like about a particular prep (grittiness/bitterness/etc.) is neither reasonable nor practical. Compounding pharmacists are the experts in determining how to formulate a product that will successfully treat an animal. In our decades of experience, we have developed a vast amount of knowledge around what makes a successful compound and the documented rationales we developed represent that knowledgebase. We disagree with any assertion that our stated reasons do not meet the requirements of GFI #256.

"While most animal patients' needs for compounded drugs can be met with patient specific prescriptions, FDA recognizes that in some cases an animal drug is urgently needed, and the time needed to compound a drug in response to an individual patient prescription may result in animal suffering or death. FDA has reviewed information concerning certain compounded drugs veterinarians need for urgent treatment. These drugs are on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals. As noted above, you have dispensed drugs containing xylazine and a combination drug containing praziquantel, pyrantel pamoate, and fenbendazole for use as office stock. The FDA reviewed information on xylazine and did not include it on the list because there are FDA-approved drugs containing the same active ingredient, in the same or similar dosage form, that can be used as labeled in horses or FDA-approved products that can be used in an extralabel manner. The FDA has not reviewed the combination of praziquantel, pyrantel pamoate, and fenbendazole for use in horses."

As noted above in Section 4, there was a processing error regarding the species for prescription no. I90039584. It was confirmed verbally with San Joaquin Veterinary Hospital on 9/26/23 this order was to be administered to kittens and puppies for deworming, not equine patients. At the time of FDA's inspection, this compound was on the "Bulk Drug Substances Currently Under Review" list and therefore allowed to be compounded for office stock for use in dogs and cats. It was moved to the "Reviewed and Not Listed" list on 11/2023 at which time we ceased

compounding for office stock. As noted above, the staff was retrained on order intake and good documentation practices to ensure they are capturing and documenting the correct species for intended use.

Additionally, as noted above in both Sections 2 and 4, we feel the prescriptions identified for xylazine in both instances are justified based on the usage and the rationale provided by the veterinarian at the time of ordering.

Should the Agency consider our response inadequate, Wedgwood Pharmacy LLC kindly requests a meeting to discuss and align with the Agency on its expectations regarding a nonbinding guidance. We will provide the Agency with monthly updates on progress of our commitments in this letter until completion.

Sincerely,

Shauna Doherty, PharmD