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Division of Pharmaceutical Quality Operations III
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Dear Dr. Garthwaite,

This letter is in response to the untitled letter dated June 10, 2024, ("Reference case: 685939"), from Rebecca E. Dowd, Program Division Director, Division of Pharmaceutical Quality Operations III. As an introductory comment, Wickliffe LLC, now known as Wedgewood Pharmacy LLC ("Wickliffe"), 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 5, 2023, November 15, 2023, December 15, 2023, and January 15, 2024.

Wickliffe 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, Wickliffe is a state licensed compounding pharmacy and not an outsourcing facility or FDA registered drug manufacturer. Accordingly, Wickliffe 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. Wickliffe 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,

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[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

"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 Wickliffe 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. Assertions Related to Health Hazard Evaluation (p.5 of Untitled Letter).

"Additionally, during the inspection on September 7, 2023, during aseptic filling of reserpine, brown residue was wiped off the bottom of vials that were introduced to the sterile hood for filling, and your root cause identified the most likely source of brown residue to be transfer of residue from shared equipment (an oven tray) that was used during production of a different drug (altrenogest) several weeks before on August 4, 2023. Your response indicated that you had hired an outside expert to conduct a health hazard evaluation (HHE) to evaluate microbiological contamination risk and cross-contamination risk; however, your HHE did not directly evaluate the microbiological contamination risk as was indicated in your response. Additionally, you failed to address potential health risks for humans when handling the vials of the other distributed batch you identified as potentially affected. Altrenogest is a synthetic hormone that is intended to affect the reproductive system in animals, and therefore may present a human health hazard (e.g., pregnant women or women of childbearing age as accidental absorption could affect the menstrual cycle or pregnancy)."

We disagree with your conclusion that the HHE did not adequately evaluate the contamination and cross-contamination risks. Wickliffe hired an outside expert to conduct a health hazard evaluation. This health hazard evaluation was performed by a veterinarian that concluded there was a "remote risk of any bio-active material inducing physiologic changes to recipients because contamination would be negligible to none." There have been no reports of adverse events or complaints associated with the 16 units that were dispensed prior to the observation. In an effort to continually improve and to enhance the HHE in response to the Untitled Letter, we hired a physician to review the documentation from the original HHE and conduct further analysis to determine the potential impact to humans. It was determined by the physician that "Given the conditions and the staffing involved, the potential for contamination was/is minimal at most. There is very minor chance for incidence of infection." Additionally, we contacted each of the 5 recipients of orders to determine

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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."

[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)).

if any humans potentially exposed to the residue experienced any potential adverse effects. None of the recipients reported any adverse effects for the handlers or for the animals that received the medication.

2. Assertions Related to Drugs for Food Producing Animals (p. 2 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 #6011175: Toltrazuril Suspension 50mg/mL – 250mL, office stock for bovine use**
- **Prescription #6021535: Tolazoline Injectable 100mg/mL – 100mL, for use in goats"**

Wickliffe does not prepare compounded medications for food-producing animals. The observation of "prescription #6011175" refers to an office stock order for veterinarian Dr. Pyle processed using our pharmacy dispensing software. Please note that as it pertains to our pharmacy dispensing software, there are patient profiles, prescription profiles, and veterinarian profiles. In our system, an order for office stock is processed with the ordering veterinarian as the "patient." This patient profile requires the selection of a "species" when setting up the profile. This field in the software has historically defaulted to "human" as the species of record and because the species field defaults to "human," our staff are required to override this default and manually select the animal species. In the case of a veterinarian ordering for office stock, we have opted to select "other" as the species. We capture the intended species for each office stock order at the time of ordering and apply that species to that specific order. Our investigation into this event revealed that in the process of manually selecting the animal species on the patient profile, "bovine" was inadvertently selected by the staff member creating the profile. Wickliffe originally received this order on January 29, 2023, prior to GFI 256 going into effect. Thus, at the time of receipt of this order, there was no recommendation in place to collect species for office stock orders, so the species was not identified on the original order. Wickliffe has subsequently audited all order records to ensure office order profiles were not assigned an incorrect species. Additionally, as part of our investigation, Wickliffe confirmed with the veterinarian on March 13, 2024, that the toltrazuril suspension 50mg/ml is for canine use. This formulation is on the bulk substances currently under review for dogs, cats, and horses, and thus is permitted to be filled for office stock orders. See the various screen shots attachments as examples of how the patient profile is set up and how species are documented for each order.

The observation of prescription #6021535 is not consistent with our SOP, a copy of which is attached to this Letter. The key points of our SOP are summarized below:

"LETTER OF INTENT:

a. Caller must fill out a LETTER OF INTENT whenever a drug is ordered for an animal that may potentially enter the food chain.

b. We do not dispense drugs to clients whose intention is to use an animal for food.

c. Do not complete an order until letter of intent is signed and sent back to pharmacy"

Per our SOP, this prescription requires a letter of intent to be completed prior to filling. This letter of intent was not received at the time of dispensing. One unit of tolazoline 100mg/mL – 100mL was dispensed to this patient. As a corrective action, a letter of intent confirming this prescription was for non-food producing animals was obtained from the prescribing practice and is stored with the original prescription. The practice confirmed the goats are non-food producing animals. A retrospective audit was conducted, and no further instances of missing Letters of Intent were discovered. As a preventive action, all order intake staff and pharmacists were retrained on this SOP, a copy of which is attached to this Letter.

3. Assertions Related to Copies of Approved or Indexed Products (pp. 2-3 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"). 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:

- **Prescription #6024501: Azithromycin in Oil Suspension 50mg/mL – 30mL**
  - **Your azithromycin (oral ROA) is a copy of multiple FDA-approved drugs including NDA 050710, which is an oral ROA drug containing azithromycin. Although your record stated that "[patient] cannot be safely pilled" and "Patient Noncompliance," we note that this approved product is not a pill, and it is not clear why the patient would be noncompliant with an approved product that is also administered in liquid form.**

- **Prescription #6024044: Pergolide Mesylate Powder 1mg/0.25TSP – 60 scoops**
  - **Your pergolide (oral ROA) is a copy of the FDA-approved drug, Prascend (NADA 141-331, 1mg pergolide mesylate tablets). Although your record stated that you compounded this product because "Concentration Adjustment Necessary," we note that there is no concentration difference between administering a 1 mg scoop of the compounded powder and administering the 1 mg FDA-approved tablet.**

- **Prescription #6020170: Cyclosporin Capsule 110 mg**
  - **Your cyclosporin (oral ROA) is a copy of multiple FDA-approved drugs including (NADA 141-218, NADA 141-329, and ANADA 200-692). The approved products are available in 10 mg capsules, 100 mg capsules, and 100 mg/mL liquid. Although your record stated that you compounded this product because "Concentration Adjustment Necessary," the same dose is available**

with a 10 mg approved capsule plus a 100mg approved capsule (total 110mg) or 1.1 mL of the approved (100 mg/mL) liquid."

Wickliffe generally does not compound copies of approved or indexed products. Consistent with the plain language of GFI #256, Wickliffe 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. Wickliffe collects a single medical rationale as determined by the veterinarian.

The observation of prescription #6024501 refers to the rationale collected. The rationale received from the veterinarian of "Patient Noncompliance" and "Patient cannot be safely pilled" we believe is entirely appropriate and consistent with the plain language of GFI #256[5]. While not required by GFI #256, we do note that the commercially available options of azithromycin suspension are cherry or banana-cherry as well as a 250mg and 500mg tablet. The prescription was written for a chicken flavored suspension for a 14-year-old feline 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 its VCPR is in the best position to determine what will best provide compliance we do not believe it is appropriate to question these decisions. We would not expect FDA to question the medical rationale provided by a veterinarian as they have no history or experience with any 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.

The observation regarding prescription #6024044 refers to the rationale collected. The rationale received from the veterinarian was "Concentration Adjustment Necessary." We understand your comment with respect to this prescription and Wickliffe will commit to reviewing the policies and procedures related to collection of medical rationale by August 15th, 2024.

The observation of prescription #6020170 refers to a rationale collected based on providing multiple capsules or an oral suspension that was on shortage at the time of dispensing. This particular compound was discontinued when research showed the product came back to market and has not been compounded since 6/6/2023. We have since retrained on our SOP to regularly confirm a commercial product is still in shortage prior to compounding. We also rely on the veterinarian and their established VCPR to determine the appropriate treatment in selecting a single capsule strength for a patient.

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[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 improved product." directly contradicts this statement in GFI #256 as it questions the veterinarian's determination.

4. Assertions Related to Office Stock (p. 3-4 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. For the time period of the review, over 200 prescriptions had "human" recorded as the species. During the inspection, you stated that you do not dispense any drugs for human use but do not routinely ask for the species in which office stock prescriptions will be used. For example, you compound the following drugs for office stock:

- **Prescription #6009627: Phenylbutazone (Alfalfa) Powder 1gm/TSP – "human" species**
- **Prescription #6018968: Doxycycline Powder 5gm/TBSP – 14 scoops – "human species"**
- **Prescription #6020609: Phenylbutazone (Apple) Powder 1gm/TSP – 500 scoops – "human species**

Additionally, for the time period of our review, the investigators observed prescriptions for a "herd" of animals that appear to be intended for larger numbers of animals than written on the prescription, indicating their use as office stock. Numerous compounded drugs were dispensed for the same group of 10 horses over a 90-day period. These drugs included: calcium levulinate/magnesium sulfate/thiamine, cyproheptadine, dantrolene, doxycycline, estradiol cypionate, flunixin meglumine, isoxsuprine, medroxyprogesterone acetate, methocarbamol, minocycline, misoprostol, omeprazole, pergolide mesylate, ponazuril, sucralfate, toltrazuril, and tryptophan. The drugs compounded for this "herd" also included quantities of drugs that would be expected to exceed the beyond use date of these drugs if used as directed:

- **Prescription #6023267: Methocarbamol 2.5gm/TBSP Powder – 100 scoops**
  - **This prescription is for a group of 10 horses with instructions to give 1 scoop orally twice daily. Thirty 100-scoop units were filled from 7/25/2023 to 8/18/2023. This amounts to a 150-day supply for 10 horses dosed at 1 scoop twice daily.**
  - **There were additional methocarbamol oral powder prescriptions filled for the same herd of 10 horses including 30 100-scoop units with a beyond use date of 12/5/2023 dispensed between 6/13/2023 and 7/14/2023. This would amount to an additional 150-day supply for 10 horses dosed at 1 scoop twice daily.**
  - **Altogether, these prescriptions amount to a 300-day supply. The period from the first prescription (6/13/2023) to the latest beyond use date (1/22/2024) is 223 days. If these prescriptions were only intended to be used in these 10 horses, treatment would be expected to exceed the beyond use date of these drugs.**
- **Prescription #6019939: Pergolide Mesylate Powder 1mg/0.25TSP – 60 scoops**

- **This prescription is for the same group of 10 horses noted above. A total of 86 60-scoop units of the pergolide oral powder (5,160 doses, 516-day supply for 10 horses dosed at 1 mg/day) were filled between 5/31/2023 and 8/18/2023.**
- **The period from the first prescription (5/31/2023) to the latest beyond use date (1/13/2024) is 227 days. If these prescriptions were only intended to be used in these 10 horses, treatment would be expected to exceed the beyond use date of these drugs.**

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 1-2 units thus showing that "large numbers of animals" are not being exposed to drugs that would not otherwise be prescribed for them.

Wickliffe does not dispense medications for human use. As noted above in section 2, our pharmacy dispensing software is also used to process office stock orders for veterinarian practices and the default species in the patient profile for office stock orders is "human." Since receiving the Untitled Letter, we have coordinated with our software vendor to update the default species setting so that "human" is no longer the default in our software instance. Notwithstanding the notation of "human" in our records, all office stock orders for which the profile was listed as "human" species were sold to veterinary offices for animal use. We have also coordinated with the software vendor to update any other office stock profiles that may have been documented as "human" in the species field to be changed to "other."

The prescriptions for "herds" are intended to be used for a group of animals in a specific, identified location consistent with GFI #256. The prescriptions for the herd indicated is located at a veterinarian's clinic and managed by one of the veterinarians. Wickliffe will commit to reviewing the policies and procedures related to population prescriptions by August 15, 2024, and adjust such policies and procedures as necessary to make sure that the amount of drug ordered is appropriate for the size of any group population meant to be treated with such compounded preparations.

5. Assertion Related to Drug Quality Violations (pp. 4-5 of Untitled Letter)

"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. Pet parents 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 pet 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.

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

"As described in GFI #256, FDA has reviewed information concerning specific antidotes, anaesthetics, and sedatives for food-producing animals and free-ranging wildlife for which 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 toltrazuril for bovine use and tolazoline for use in goats. FDA has not reviewed information concerning toltrazuril or tolazoline for use in these species."

As noted in Section 2 above, Wickliffe does not compound drugs for food-producing animals. Any notations in our system to the contrary were mistakes.

"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 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. 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 drugs 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."

As noted above we disagree that the medical rationales provided by veterinarians and documented by Wickliffe 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 Wickliffe 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 pet. 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 could result 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 pergolide and methocarbamol for use as office stock. FDA reviewed information concerning pergolide and methocarbamol for use in horses and did not include them on the list because there is an FDA-approved drug 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."

With respect to the identified pergolide orders, the orders were placed as a prescription for a herd. The Agency has determined the orders to be for office stock due to perceived non-compliance with GFI 256, however we note that this drug was moved to the "not-listed" list on May 2, 2023, and Wickliffe filled orders on May 31, June 8, June 27 and June 28, 2023. We received correspondence from Amber McCoig of FDA's Center for Veterinary Medicine, a copy of which I attached hereto, confirming that we would be able to continue to make and sell product placed on the "not-listed" list for 60 days after such placement. Accordingly, even if these orders are to be considered office stock, these sales of pergolide were consistent with direction we received from the Agency.

One final note, during the September 2023 inspection of Precision Equine LLC, if the Agency shared similar GFI related comments, then we want to emphasize that the Corrective Actions noted in this response have been or will be implemented at this facility and the pharmacy formerly known as Precision Equine LLC. 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,

Nicholas Kirkpatrick, PharmD