



**International Academy
of Compounding Pharmacists**

P.O. Box 1365
Sugar Land, Texas 77487

281/933-8400 voice
281/495-0602 fax
1-800-927-4227

www.iacprx.org
iacinfo@iacprx.org

June 15, 2004

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket No. 2003D-0290
Guidance on Compounding of Drugs for Use in Animals**

To Whom It May Concern:

The International Academy of Compounding Pharmacists (IACP) is greatly concerned with the absence of almost 2,500 commentary letters from the FDA Docket. These letters address FDA's revision to Compliance Policy Guide (CPG) Manual Section 608.400 entitled, "Compounding of Drugs for Use in Animals."

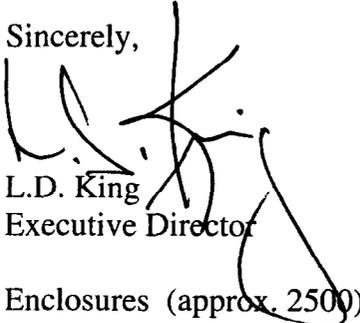
IACP submitted initial comments on this guidance to FDA's Center for Veterinary Medicine (CVM) during a meeting on September 16, 2003. These comments have never been appended to the Docket. We have attached a copy of our commentary. Please ensure that IACP's comments are added to the Docket.

Further, IACP has received copies of thousands of letters sent to FDA CVM from pharmacists, veterinarians, and pet owners. Although CVM has confirmed the receipt of many of these letters, very few to none of these letters have been added to the docket. We are likewise providing copies of these letters for inclusion in the Docket.

Included are approximately 250 letters from pharmacists, 550 letters from veterinarians (including over 200 original, non-form letters), and 1650 letters from pet owners (including 50 original letters). Each letter testifies to the importance of compounding in preserving the health and well being of non food animals.

Please ensure that all attached documentation is added to the FDA Docket.

Sincerely,


L.D. King
Executive Director

Enclosures (approx. 2500)

2003D-0290

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September 16, 2003

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket No. 2003D-0290
Guidance on Compounding of Drugs for Use in Animals**

Dear Sir or Madame:

On behalf of the International Academy of Compounding Pharmacists ("IACP"), we submit these comments on the Compliance Policy Guide ("CPG") Manual Section 608.400, entitled "Compounding of Drugs for Use in Animals" ("guidance"), issued by the Food and Drug Administration ("FDA"). IACP is dedicated to increasing awareness of the importance of compounding by providing accurate information on the benefits of compounding, and to assisting pharmacists in improving their compounding practices. In this capacity, IACP wishes to address a number of issues in the guidance. IACP submits these comments on behalf of its 1,800 members, who are primarily compounding pharmacists, many of whom compound prescriptions for animals.

I. The Guidance Should Not Have Been Issued Without Opportunity for Prior Comment.

FDA inappropriately issued and immediately implemented CPG 608.400 as a final, Level 1 guidance without an opportunity for prior public comment. FDA's classification of the guidance as Level 1 demonstrates that the agency considers the guidance to be significant, since, under these circumstances, a Level 1 guidance "set[s] forth . . . changes in interpretation or policy that are of more than a minor nature." 21 C.F.R. § 10.115(c)(1)(ii). We agree with this classification. The guidance document will affect the

practices of thousands of veterinarians and compounding pharmacists across the country who are seeking to lawfully provide medications for a population – food-producing, companion, and exotic animals – that is woefully underserved by the commercial drug manufacturing industry.

Pursuant to FDA regulations, the procedure for issuance of a draft Level 1 guidance document is for a draft to be prepared and issued. 21 C.F.R. § 10.115. FDA must then publish notice of the guidance, make a copy available, and invite public comment on the draft. *Id.* This procedure is consistent with Congressional intent to allow public input in the development of a guidance document.

In order to ensure public participation in the development of policies, FDA developed regulations establishing the procedures it would follow in the issuance of guidances. Pursuant to this regulation, an exception to the requirement for FDA to seek public input prior to implementation of a Level 1 document occurs only when “the agency determines that prior public participation is not feasible or appropriate.” 21 C.F.R. § 10.115(g)(2). In the preamble to issuance of this final regulation, in response to comments about the exception, FDA described the circumstances when it anticipated this exception would be used. *See* 65 Fed. Reg. 56,468 (Sept. 19, 2000). FDA described three situations: (1) “public health reasons for the immediate implementation of the guidance document;” (2) “statutory requirement, executive order, or court order that requires immediate implementation,” or (3) “the guidance document presents a less burdensome policy that is consistent with public health.” 65 Fed. Reg. at 56,472 (emphasis added). None of these circumstances is present here.

The agency gives, as its reason for not soliciting prior public comment, an “urgent need to explain how, in light of a recent court decision and revised policy regarding drugs for human use, it intends to exercise its enforcement discretion regarding compounded drugs for animal use.” 68 Fed. Reg. 41,591 (July 14, 2003). However there was no “urgent need” for FDA to do anything. The “recent” court decision referred to by the agency was actually issued 15 months ago, and the “revised policy regarding drugs for human use” was issued over a year ago. Note also that this CPG does not implement any court’s decision. Thus, pursuant to FDA’s own regulation, prior public participation is required unless it is not “feasible or appropriate” to solicit prior public input. Given that the court decision was issued 15 months ago and did not direct FDA to do anything, there is no reason why the agency could not have permitted the public to respond to a draft guidance and then addressed these comments in a final guidance.

Further, issuance of CPG 608.400 as a guidance policy that is immediately effective, without opportunity for prior public input, is completely inconsistent with Congressional intent, expressed in the legislative history for the bill that became section 701 of the Federal Food, Drug and Cosmetic Act ("FDCA"). The House Report for this bill stated that the requirement for prior public participation be waived by the Agency only "in rare and extraordinary circumstances where there is a compelling rationale."¹

The lack of urgency in issuing this guidance is also demonstrated by reviewing the circumstances where the agency has correctly determined that urgent, rare, and extraordinary circumstances exist. Two guidance documents, "Food Producers, Processors, Transporters, and Retailers: Food Security Preventative Measures Guidance," and "Importers and Filers: Food Security Preventative Measures Guidance," were prompted by concerns about food safety and security in light of terrorist activities, following the September 11, 2001 tragedies. See 68 Fed. Reg. 13,931 (Mar. 21, 2003). The "Guidance on the Petition Process to Request Approval of Labeling for Foods That Have Been Treated By Irradiation" was implemented following enactment of the Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, 115 Stat. 2384. In that instance, section 10809 of the act was in effect and there was a "pressing need" for the guidance. 67 Fed. Reg. 62,487, 62,488 (Oct. 7, 2002).

No emergent public health issue has been identified to warrant immediate implementation of this CPG. The court decision referred to by the agency, Thompson v. Western States Medical Center, occurred almost 15 months before issuance of the CPG and did not identify any urgent public health issue requiring immediate implementation of a compliance guidance. See Thompson v. Western States Medical Center, 535 U.S. 357 (2002). Thompson involved a challenge to a ban on the advertising of compounded drugs, in which the Supreme Court affirmed the Court of Appeals judgment that the restriction of advertising was an unconstitutional violation of free speech. Id. The agency had over one year in which to solicit public comments by holding meetings or workshops or to publish a proposed guidance and did not do so.

Moreover, no statutory requirement, executive order, or court order has been issued that requires immediate implementation of a CPG without public input. The recently issued

¹ H.R. Rep. No. 105-310, at 74 (1997).

CPG references the Animal Medicinal Drug Use Clarification Act of 1994 as the source of the factors FDA will use for enforcement discretion. No new or recent authority is cited.

Finally, the current guidance document does not present a less burdensome policy than previously existing policy. Indeed, the unnecessary, unreasonable, and unjustified restrictions on animal compounding expressed in the CPG will be discussed in detail below.

The exception to the requirement for public participation for implemented Level 1 type documents is analogous to the exception when a notice and comment period is not required for rulemaking under the Administrative Procedure Act (APA).² As courts have held, the exception from the requirement for notice and comment was “an important safety valve to be used where delay [for public comment] would do real harm . . . [but] not to be used [just] to circumvent the . . . requirements whenever an agency finds it inconvenient.” United States Steel Corp. v. U.S. Env'tl. Prot., 595 F.2d 207, 214 (5th Cir. 1979). Further, courts have generally held that an exception to the APA notice and comment requirement should only be “narrowly construed” and “reluctantly countenanced.” N.J. Dept. of Env'tl. Prot. v. EPA, 626 F.2d 1038, 1045 (D.C. Cir. 1980). When determining whether public notice and input is impractical or unnecessary, courts have examined the facts of the situation to establish whether there is “good cause . . . supported by more than a bare need to have regulations . . . especially in the context of health risks . . . [to] assure . . . dialog necessary to the creation of reasonable rules.” Nat'l Ass'n of Farmworkers Organizations v. Marshall, 628 F.2d 604, 621 (1980). In the present circumstance, no “real harm” would have resulted and no “good cause exists” for implementing CPG 600.408 without prior public dialogue.

By implementing this CPG without public comment the agency prevented public participation in the development of the guidance document. There was no compelling or emergent public health need. There was no statutory requirement or court order requiring immediate implementation, and the CPG is not a less burdensome guidance. There were no “rare or extraordinary circumstances.” FDA should have issued the CPG as a draft, and permitted the public to respond, prior to implementation. IACP takes strong exception to the issuance of this document without any prior chance for public comment. We believe that FDA should withdraw the CPG and reissue it as a draft to allow for public

² 5 U.S.C. § 553

participation. Submitting comments after the fact is simply no substitute for public input prior to the CPG's adoption.

II. The Guidance Should Not Include a Blanket Prohibition on Compounding of Veterinary Drugs from Bulk Substances.

The guidance contains what is, in essence, a prohibition on the use of bulk chemicals in veterinary compounding, even bulk chemicals that are active ingredients in approved animal or human drugs, and even when the compounded drug will not be used to treat food-producing animals.

This unreasonable restriction must be examined from the perspective of the importance of veterinary compounding, including compounding with bulk chemicals, for a population that simply cannot always be treated using commercially available medications. The guidance itself recognizes that the compounding of drugs for animals is within "the bounds of traditional pharmacy practice." Guidance at 3. FDA itself has repeatedly recognized the importance of compounding drugs for animals, inasmuch as the veterinary industry is significantly underserved by existing commercially available and grandfathered drugs. In the guidance, FDA states, "The current state of veterinary medicine requires products to treat many conditions in a number of different species, some of which are known to have unique physiological characteristics." *Id.* The reality is that, if compounders are limited to using FDA-approved, commercially available drugs, many animals will die, go untreated, or suffer needlessly.

In many instances, FDA's broad restriction against the use of bulk drug substances to compound for animals would be detrimental to animal health and to the practice of good veterinary medicine:

First, FDA's restriction against veterinary compounding from bulk drug substances fails to account for commercial products that have been withdrawn from the market for economic reasons and not for reasons of safety or effectiveness. Drug companies discontinue products for many reasons unrelated to safety, such as market position or profitability. The election by a drug manufacturer to stop selling an unprofitable but safe drug should have no impact on the ability of pharmacists to compound that drug to fill prescriptions. In fact, the ability of a pharmacist to compound such drug products has saved many human and animal lives. FDA's CPG for human drug products allows the compounding of drugs that were discontinued for reasons other than safety or efficacy. The veterinary CPG should be at least as flexible.

Cyclosporine provides a prime example of such a drug product. Cyclosporine is an ophthalmic product indicated for treatment of chronic keratoconjunctivitis sicca (KCS) in dogs. The product was formerly manufactured as Optimmune® by Schering-Plough. However, it has been discontinued due to economic constraints on the manufacturing company. Pharmacists can compound cyclosporine ointment to fill the void left by Optimmune's discontinuation. However, elimination of cyclosporine, USP powder would eliminate pharmacists' ability to compound this product and would considerably jeopardize treatment of dogs with this disease. If left untreated, KCS can threaten the vision of dogs. In advanced disease states, it may lead to painful corneal ulcerations and vision may become impaired due to scarring of the cornea.

In addition, using finished dosage forms, such as tablets, to compound sterile dosage forms (i.e. ophthalmic drops, injectables, etc.) may add unnecessary excipients to the compound and increase the risk of pyrogen contamination in the product. Pure active pharmaceutical ingredients are best suited for use in these customized formulations.

As an example, miconazole ophthalmic solution for treatment of animal patients with fungal keratitis is an essential compounded product that would be eliminated under the current FDA guidance. Elimination of miconazole, USP powder would substantially jeopardize the treatment of animal patients with fungal keratitis. No commercially available products are suitable for topical use in the eye, and are, in fact, quite damaging to the eye due to preservatives and vehicles used in commercially available miconazole products. A suitably compounded miconazole 1% sterile ophthalmic solution is the treatment of choice for equine fungal keratitis. The only approved topical antifungal ophthalmic suspension, Natacyn (natamycin) is irritating to equine eyes and is not effective against filamentous fungal agents commonly seen in equine veterinary practice. Without compounded miconazole ophthalmic solutions, loss of the equine eye would result. Many animals would unnecessarily become unsound and potentially be euthanized.

Further, compounded dosage forms are often used in animal and human patients when there is no commercial alternative to treat the diagnosed disease state or medical condition. FDA's Center for Drug Evaluation and Research (CDER) has repeatedly recognized compounding from bulk drug substances as a valid practice for treatment of human patients. IACP sees no reason why FDA's Center for Veterinary Medicine (CVM) should enforce a more stringent standard, especially for non-food producing, exotic, and companion animals.

As an example, cisapride, a benzamide prokinetic agent, is a compounded veterinary product that is widely recommended as part of the medical management of megacolon in cats. Recent experimental work (Washabau, 1994) using feline colonic smooth muscle has demonstrated that:

- (i) Cisapride stimulates contraction of both longitudinal and circular smooth muscle from both the proximal and distal colon;
- (ii) Cisapride's actions are only partially dependent on enteric cholinergic neurones;
- (iii) Cisapride can activate a direct smooth muscle response;
- (iv) Cisapride's actions on colonic smooth muscle are dependent on extracellular calcium; and
- (v) Other "motility enhancing" drugs such as domperidone, motolin, erythromycin, and metoclopramide have no effect on feline colonic smooth muscle in vitro.

In other words, there are no substitutes for cisapride in cats with megacolon. Hundreds of cats are dependent upon lifetime treatment with cisapride to maintain colonic motility, and without cisapride therapy, many of these cats would have to be needlessly euthanized.

Another example involves compounded drug products used to treat epilepsy. There were an estimated 60 million pet dogs in the United States in 2002. The prevalence of epilepsy in the canine population is about 1%, meaning that nearly 600,000 dogs in the U.S. have epilepsy. Potassium bromide has become the drug of choice for management of canine epilepsy, rapidly replacing phenobarbital. This widespread use is due to potassium bromide's greater safety, decreased side effects, and lack of potential for human abuse as compared to phenobarbital. Epileptic dogs must be maintained for life on potassium bromide. Were potassium bromide to be denied to the epileptic population, hundreds of thousands of dogs would experience breakthrough seizures and a tremendous degree of unnecessary suffering. Compounded potassium bromide is essential to the health of many companion-animal dogs. FDA's outright ban on compounding veterinary products from bulk drugs would eliminate this vital therapy and bring unnecessary suffering to many pets and owners.

Finally, compounded dosage forms are often used to improve therapeutic outcomes in patients by customizing compliance elements of the therapy such as concentration or flavor. Although such compliance elements may initially seem not to be clinically significant, it would be virtually impossible to administer necessary medications to many animals without the availability of compounded dosage forms that have been customized to increase patient compliance. Many animals would be subjected to unnecessary suffering,

and at times death, if compounded medications became unavailable to treat their unique medical conditions. Manipulating commercially available, finished dosage forms to compound such therapies may limit the possible routes of administration, concentration of dosage forms, or flavor of the product, making a medication too difficult to administer or unpalatable. The need for customized therapies is especially evident when considering the unique medication needs of exotic animals. Exotic animals exhibit tremendous diversity in size and features. They range from parrots to elephants, poison dart frogs to lions. The unique attributes of many exotic animals require customized therapies. Without compounding, the medications needs of these unique veterinary patients would be left unfulfilled and the death or mutilation of many animals would result. Pharmacists should not be prohibited from compounding veterinary products to meet compliance needs, especially when the benefits to the patient outweigh the risk to the patient and to the community. This is true for all animals, and particularly for companion and exotic animals.

These are only a few of the many examples of cases that require compounding for animals from bulk drug substances. As demonstrated, if FDA were to continue to prohibit all compounding from bulk drug substances, a tremendous degree of mutilation, suffering, and death of animal patients would result. FDA would be remiss if it did not recognize this fundamental flaw in its prohibition against the use of bulk drug substances in veterinary compounding, especially when Congressional intent demonstrates a clear commitment to preserving access to bulk drug substances in compounding.

The principal legislation affecting the compounding of drugs for animals was the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). As stressed by the primary sponsor of this legislation, Senator Howell Heflin, the purpose of AMDUCA was to clarify that veterinarians could continue to engage in the off-label use of animal drugs or human drugs. As Senator Heflin put it, the Act "will not increase or alter overall patterns of drug usage by veterinarians." 139 Cong. Rec. 1447 (1993).

Indeed, compounding has always been an accepted practice of pharmacists. *Remington's Practice of Pharmacy*, relied on for decades as the "Bible" of pharmacy operations, described, as long ago as 1936, the practice of pharmacy as requiring a "knowledge of medicines and the art of preparing and dispensing them," as well as knowledge of "their identification, selection, preservation, combination, analysis and standardization . . . *Compounding* consists of the skillful blending of two or more ingredients." *Remington's Practice of Pharmacy I* (8th ed. 1936) (emphasis in original). The United States Pharmacopeia – the official compendium of drug information recognized as authoritative by the federal Food, Drug, and Cosmetic Act (FDCA) – has included

instructions on compounding medications since 1920. *History and Background Information on USP's Activities in Compounding Pharmacy Practices*, 27 Pharmacopeial F. 3169 (2001). The laws of nearly every state define the practice of pharmacy to include compounding.

In the very case cited to justify the issuance of this CPG without comment, the United States Supreme Court has likewise recognized the importance of compounding, again, in reciting principles that are no less applicable to animals than to humans.

The Government . . . has an important interest . . . in permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs. And it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for the new drug approval process. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so requiring such testing would force pharmacists to stop providing compounded drugs. Given this, the Government needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing. That line must distinguish compounded drugs produced on such a small scale that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so.

Western States, 535 U.S. at 369-70.

The principles enunciated by the court in the recent decision of In re Wedgewood Village Pharmacy, Inc., No. 03-2049, 2003 U.S. Dist. LEXIS 11648, at *61 (D.N.J. July 7, 2003), also apply equally to veterinary pharmacy compounding as to compounding for humans: "FDA has recognized the essential need for individually tailored medication and the economic realities that those individually tailored medications would not be available if pharmaceutical compounding had to meet the new drug requirements."

There can be no doubt that compounding from bulk chemicals is historically the mainstay of the practice of pharmacy. Indeed, in 1938, when the FDCA was passed, relatively few final dosage forms were available, and pharmacists compounded more than 250 million prescriptions annually. *Proceedings of the Local Branches*, 14 J. Am. Pharm. Ass'n 232, 233 (1935). Nearly all of these prescriptions were compounded from bulk chemicals.

In light of this support for the widespread and traditional practice of compounding from bulk chemicals and the critical inadequacy of commercially manufactured drugs to treat animal illness and suffering, it makes no sense to restrict veterinary compounders from engaging in the very practices that compounders of human drugs are permitted to engage in. In the absence of an Investigational New Drug Application, the CPG on human compounding prohibits compounding from bulk chemicals only when those “bulk active ingredients . . . are not components of FDA approved drugs.” CPG Sec. 460.200. Likewise, the veterinary CPG must be revised to ensure that the universe of bulk active ingredients available for use in compounded veterinary drug products includes, at minimum, those bulk active ingredients that are components of approved or grandfathered human or animal drugs. Taking a more restrictive approach to animal compounding so that all bulk compounding is prohibited, however, is illogical, and contrary to good animal care.

Other provisions in the guidance address the agency’s concerns about the use of compounding to avoid compliance with current good manufacturing practice regulations applicable to drug manufacturers. This can be addressed with more narrowly crafted restrictions. The appropriate restrictions to impose on compounders to achieve this goal, keeping in mind the critical nature of compounding activities to providing medications necessary to protect the health and welfare of animals, are that compounded prescription drugs only be distributed pursuant to the lawful order of an appropriately licensed health-care practitioner, the prohibition on compounding drugs that are commercially available, and the requirement that compounded drugs only be produced and distributed when the “health of the animal” is “threatened,” and where “failure to treat” would likely result in “suffering or death of the animal.” These provisions, unlike the ban on use of bulk drugs, are consistent with the intent of Congress in passing the bill that became AMDUCA.

FDA tries to support its blanket prohibition on the compounding of veterinary drugs by relying on the holdings of United States v. Algon Chemical, 879 F.2d 1154 (3d Cir. 1989) (“Algon”) and United States v. 9/1 kg Containers, 854 F.2d 173 (7th Cir. 1988) (“Schuyler”). However, these decisions address only compounding by veterinarians, not compounding by licensed pharmacists, as the guidance itself recognizes (“the Act does not permit veterinarians to compound unapproved finished drug products from bulk drug substances”). Although the guidance states that the principle of these cases “applies equally to compounding by pharmacists,” this simply is untrue.

State laws and state agencies authorize, inspect and regulate the compounding practices of state-licensed pharmacies, but do not do so with veterinarians. Pharmacists

only compound veterinary prescription drugs upon the direction of veterinarians, and two state-licensed professionals are thus involved in determining whether a compounded product is appropriate, safe, and effective. Veterinarians compounding on their own have no check or balance on their compounding practices. Moreover, compounding is an integral, long accepted part of the practice of pharmacy, but not of veterinary medicine. Accordingly, the two court decisions granting FDA power to prohibit compounding from bulk drugs by veterinarians cannot be applied to support such a prohibition on pharmacists.

To apply the prohibition to the use of bulk drugs in compounding for non-food-producing animals is especially nonsensical. The guidance cites AMDUCA as being the important legislation on this area, yet the legislative history of AMDUCA demonstrates unequivocally that Congress, before approving AMDUCA, was intent on protecting the ability to compound for the animal population, and that any restrictions on animal-drug compounding were targeted primarily – if not exclusively – on preventing harmful residues from being created in food-producing animals. For example, Senator Howell Heflin, the primary sponsor of AMDUCA, stated that the bill “gives FDA full access to the tools necessary to assure the continue[d] safety of the food supply and to keep unwanted and illegal residues of animal drugs from contaminating our food.” 140 Cong. Rec. 14071 (1994). Earlier, Senator Heflin noted that AMDUCA would permit “[v]iolators who cause the presence of illegal residues in food” to be prosecuted appropriately. 139 Cong. Rec. 1447 (1993).

Therefore, the blanket restriction on compounding from bulk chemicals contained in this guidance should be revised to allow, at minimum, the use of bulk active ingredients that are components in an approved or grandfathered animal or human drug. Some restrictions on the bulk drug substances used to compound for food-producing animals may be appropriate, but a flat ban on the use of bulk drugs is clearly detrimental to good veterinary healthcare.

III. Several Components of the Guidance, Including the Irrational Prohibition on Anticipatory Compounding and the Prohibition of Compounding Pharmacists’ Use of Commercial-Grade Processing Equipment, are Wrong.

A number of the other factors included in the guidance, intend to warn compounders when FDA will take enforcement action, are problematic.

Factor 2: The second factor listed in the guidance indicates that FDA will consider enforcement action when a pharmacy engages in “[c]ompounding of drugs in anticipation

of receiving prescriptions, *except in very limited quantities* in relation to the amounts of drugs compounded after receiving valid prescriptions.” Guidance at 4 (emphasis added). This statement represents a significant change from FDA’s prior position in its 1996 Compliance Policy Guide for Compounding of Drugs for Use in Animals, CPG Sec. 7125.40, which stated that FDA would consider enforcement action if a pharmacy engaged in “preparation for sale of large quantities of unapproved new animal drugs on an ongoing basis and where no valid medical need or VCPR [Valid Veterinarian-Client-Patient Relationship] exists.” IACP believes that the change of conditions under which anticipatory compounding is allowed is unduly restrictive and significantly inhibits the ability of compounding pharmacists to run effective practices and to meet their patients’ needs.

The phrase “very limited” may lead FDA to take action based on what has been regarded as acceptable anticipatory compounding, or cause pharmacists to unduly curtail legitimate anticipatory compounding based on historical prescribing patterns. This section should be revised to permit anticipatory compounding in “limited quantities based on historical prescribing patterns and appropriate beyond-use dating as determined by State Boards of Pharmacy or the United States Pharmacopeia Chapter 795.”

Anticipatory compounding is a well-accepted, beneficial component of traditional compounding. See, e.g., Ohio Admin. Code § 4729-9-21 (2003) (“A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns”); 22 Tex. Admin. Code § 291.31 (2003) (defining compounding to include “[t]he preparation, mixing, assembling, packaging, or labeling of a drug or device: . . . in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns”). See also National Association of Boards of Pharmacy, Model State Pharmacy Act and Model Rules, Good Compounding Practices Applicable to State Licensed Pharmacies, App. C, Subpart A (“NABP Model Rules”). The NABP Model Rules state that:

Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy (as required by State law). The compounding of inordinate amounts of drugs in

anticipation of receiving prescriptions without any historical basis is considered manufacturing.

NABP Model Rules at App. C, Subpart A. Although the NABP guidelines refer to “very limited quantities,” they specifically reference a history of prescription patterns to determine what is a “very limited quantity.” Further, the NABP guidelines state that a pharmacist is engaged in manufacturing only when the pharmacist compounds “inordinate amounts of drugs” in anticipation of prescriptions and there is no historical basis for the anticipatory compounding. Thus, the NABP guidelines use relative context of historical practice, whereas the CPG uses the more restrictive, absolute standard of “very limited.”³

Additionally, this factor could have negative effects on drug quality if it forces pharmacists to compound multiple small batches of a drug product as opposed to a single, large batch. Producing multiple small batches of drug products may incur a greater risk of error and contamination than preparing a single batch of greater quantity. Compounding in larger batches also permits sterile compounding pharmacies to conduct sterility testing in advance of receiving prescriptions, thereby enabling pharmacies to test the sterility (and other attributes) of the compounded product prior to releasing the product to the consumer. Patient-by-patient compounding precludes this testing. FDA investigators have cited pharmacists for not testing every batch of compounded drug. Demanding that type of testing is incompatible with the virtual preclusion of anticipatory compounding. Allowing pharmacists who receive regular prescriptions for a drug the flexibility to compound sufficient quantities of that drug could enhance quality and lead to greater efficiencies.

Factor 6: The sixth factor addresses the use of “commercial scale manufacturing equipment for compounding drug products.” Guidance at 5. The restriction on commercial scale equipment is a source of concern. The CPG provides no bright-line test to determine whether a particular piece of equipment is of “commercial scale.” Some pharmaceutical manufacturers make small quantities of certain drug products (e.g., orphan drugs). There may be some overlap in scale or quantity in equipment that a manufacturer possesses and the equipment that a compounding pharmacist who receives numerous prescriptions might need to operate his or her business effectively. This pharmacist could potentially buy smaller equipment and produce several small batches of the drug. However, smaller,

³ As stated above, we also recommend removing the modifier “very” as unnecessarily restrictive.

repeated batches pose a greater risk of error than a single, large batch, and means less efficient use of pharmacists. IACP recommends that the FDA remove this language in the CPG.

Also, FDA should never use sophistication of equipment as a surrogate endpoint for whether a pharmacy is a manufacturer. Pharmacists who use advanced technology will have an enhanced ability to compound properly. More pharmacists are using automated equipment, such as automated mixing bowls and dispensing equipment, to facilitate compounding and increase the quality of compounded drugs. FDA should not confuse scale, which relates to volume and quantity, with sophistication or complexity, which relates to quality. This factor should be clarified in the revised CPG.

Factor 8: The guidance is also overly restrictive when it states that any failure to “operate in conformance with applicable state law regulating the practice of pharmacy” can place a pharmacy at risk of enforcement action by FDA. While IACP agrees that pharmacists must act in conformance with applicable pharmacy laws, FDA should clarify that this factor relates to those aspects of state pharmacy law that indicate whether the pharmacy is acting as a manufacturer. State boards of pharmacy impose numerous requirements on pharmacies, such as the need to pay its registration fee in a timely manner,⁴ establishing a pharmacist to pharmacy technician ratio⁵ and the need to notify the board of pharmacy of the designated pharmacist-in-charge.⁶ There are numerous other requirements of state pharmacy law that have no bearing on whether a pharmacy is acting as a manufacturer. The failure to comply with every single element of a statute or regulation does not mean that a pharmacy is a manufacturer. Thus, if a specific state law violation indicates that a pharmacy is a manufacturer, it may be appropriately considered by FDA in assessing a pharmacy’s status. Enforcement for other types of violations should rest solely with the State Boards of Pharmacy.

⁴ See, e.g., Cal. Bus. & Prof. Code §§ 4400, 4401 (Deering 2003); Cal. Code Regs. tit. 16 § 1749 (2003).

⁵ See, e.g., Cal. Bus. & Prof. Code § 4115(g) (Deering 2003); Cal. Code Regs. tit. 16 § 1793.7(f) (2003).

⁶ See, e.g., Cal. Bus. & Prof. Code § 4113(a) (Deering 2003); Cal. Code Regs. tit. 16 § 1709 (2003).

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IACP appreciates the opportunity to comment on the CPG, and trusts that its comments will be seriously considered by the agency. We regret, however, that these comments are being provided after issuance of the CPG, as opportunity for prior comment was not provided.

Due to the lack of FDA compliance with Good Guidance Practices in issuance of this CPG and the severe and immediate impact of this guidance on veterinary healthcare, IACP requests that CPG Manual Section 608.400 be withdrawn and reissued in draft form to allow public comment and revision of the guidance before implementation.

Please do not hesitate to contact me if you have any questions.

Respectfully submitted,

L.D. King
Executive Director

**Letters to FDA
From Pharmacists**

Docket # 2003D-0290

*Copy for
Lobbyst*



Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HIV-1)
7500 Standish Place
Rockville, MD 20855

COLLEGE OF PHARMACY
April 29, 2004

Dear Dr. Sondlof:

I am writing you in reference to the Compliance Policy Guide (CPG) issued for the Animal Medical Drug Use Clarification Act (AMDUCA). My understanding is that this CPG was issued in final form, without allowing opportunity for comments, in violation of FDA Good Guidance Practices. I am urging you to rescind this CPG and re-issue it in draft format for review and comment by the interested public.

In particular, FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals lacks foresight. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. For example, just last Tuesday, a veterinarian called the hospital where I work looking for dexamethasone sodium phosphate for a dog that he believed suffered a stroke. The hospital didn't carry it. However, a compounding pharmacist would have it, as a USP bulk chemical. The reason the hospital didn't have it (along with many other steroids) was because it was in short supply from manufacturers. This is just one example of how compounding could benefit non-food producing animals.

Medicine, both veterinary and human, is changing rapidly and with the advent of pharmacogenetics, manufacturers will not be able to supply every drug in every dose or form needed, it just won't be economically feasible for them to do so. Pharmacists are highly educated (6 years of training) and capable of providing a quality product to the public. Regulators should focus on improving standards and accreditation of pharmacies to fulfill the needs of veterinarians. The goal should be to bring the pharmacies up to the highest standards possible, not to prevent them from serving a true medical need.

Sincerely,

Catherine A. Harrington, PharmD, PhD
Associate Professor
Nova Southeastern University
College of Pharmacy

cc: Mark McClellan, FDA Commissioner; cc: The Honorable Senator Graham and The Honorable Senator Nelson IACP

HEALTH PROFESSIONS DIVISION
COLLEGE OF PHARMACY - WEST PALM BEACH PROGRAM

3970 RCA Boulevard, Suite 7006 • Palm Beach Gardens, Florida 33410 • (561) 622-8682 • Fax (561) 622-9205

March 19, 2004

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

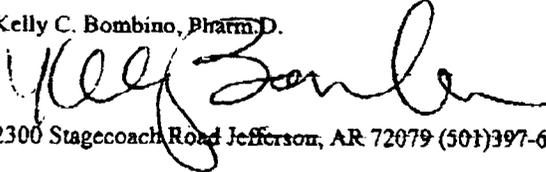
I am writing you with concerns over regulations implemented by the FDA regarding the Animal Medicinal Drug Use Clarification Act of 1994. CVM's issuance of the Compliance Policy Guide (CPG) was in final form without allowing the opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are tremendously concerning and deserve a comment period before being put into effect.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is **EXTREMELY PROBLEMATIC**. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Many of the medications compounded for family's pets are only available in this form and inaccessibility to them would cause undue suffering and illness.

It is interesting that the compounding of medications for HUMANS from bulk chemicals is deemed legal, ethical and safe as recognized by the FDA Modernization Act of 1997's section 503A. Why should our pets be denied the same chance at quality of life?

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Kelly C. Bombino, Pharm.D.


2300 Stagecoach Road Jefferson, AR 72079 (501)397-6196

cc: Mark McClellan, MD, Ph.D., FDA Commissioner

cc: Blanch Lincoln, Arkansas Senator

cc: Mark Pryor, Arkansas Senator

cc: Vic Snyder, Arkansas Representative

cc: International Association of Compounding Pharmacists

**BOOTHWYN PHARMACY, INC.**

March 1, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food & Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Sir,

I am gravely concerned about compliance policy guidelines recently passed in their final form that directly affect my veterinary compounding business for non-food producing animals. These changes are egregious in nature not only for their content but in the manner that they were actualized.

To disregard input from the pharmacy community is irresponsible and in direct violation of your own department's Good Guidance Practices. These guidelines are wide sweeping and encompass all aspects of compounding causing quite a problem for the community pharmacist who cares for and treats small household animals and non-food producing animals.

As such a pharmacist, I respectfully and stridently, ask that these guidelines be withdrawn and reissued in a draft form taking into consideration all aspects of veterinary compounding. Our livelihood is dependent upon these guidelines being revoked.

In a democratic society, rules are created to govern and guide the populace. When a governing body acts in disregard of said populace the basic tenets of this country are in jeopardy. Please rectify this action in a fair and equitable manner.

Sincerely,

Louis M. Micolucci, R.Ph.
BPI-Vet, Division of Boothwyn Pharmacy, Inc.

Cc: Mr. Mark McClellan, FDA Commissioner, #301-443-8100
Senator Arlen Specter, Philadelphia District Office #215-597-0406
Senator Rick Santorum, Pittsburgh District Office #412-562-4313
Congressman Joseph Pitts, Unionville District Office #610-444-5250
Congressman Jim Gerlach, Glenmoore District Office #610-458-8389
Congressman Curt Weldon, Philadelphia District Office #215-596-4655
IACP, #281-495-0602
Dr. Michael Chaddock, Director, AVMA, Government Relations #202-842-4360



Compounding Pharmacy
2801 Millwood Ave. 8810 Farrow Road
Columbia SC 29205 Columbia SC 29203
(803) 765-2672 (803) 736-5975
Wendy J. Lee, PharmD

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen F. Sundlof,

Each patient who approaches our pharmacies has a specific need to be met through medication. In certain cases this need will be achieved by prescription compounding from *quality* bulk chemicals. These situations should not only include the human population but also our diverse animal communities. Example cases include; using flavors to make medications more appealing to a household pet, creating the most appropriate dosage in a capsule or troche instead of the owner needing to administer partial tablets, treating a difficult pet with a medicated transdermal gel in place of an injection or oral drug, and compounding a dosage form of a discontinued or temporarily out-of-stock medication when the human preparation is no longer available. By compounding medications we can help meet each animal's unique need.

With these thoughts in mind we at Long's Pharmacy are very concerned about the Compliance Policy Guide (CPG) issued by the Center for Veterinary Medicine. The CPG was issued in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is tremendously problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

For a healthy quality of life of these animal populations Long's Pharmacy asks the FDA to withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and patient owners to comment on it before it is implemented. Thank you for your understanding of this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Wendy Lee". The signature is fluid and cursive, with a large, stylized "W" and "L".

Wendy Lee, PharmD

cc: Mark McClellan, FDA Commissioner
cc: Senator Lindsey Graham, US Senate (R-SC)
cc: House Representative Joe Wilson, US House (R-SC)
cc: IACP



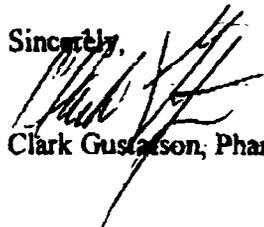
Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U. S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I am disappointed that CMV recently issued a Compliance Policy Guide (CPG) in final form, not allowing for comments. I believe this is in violation of FDA Good Guidance Practices. Several requirements of this CPG deserve a comment period before a final CPG is put into effect. Among these requirements in the CPG is a prohibition against compounding from bulk drug substances. This is troublesome. Pharmacists should be allowed to compound for non-food producing animals from bulk drug substances. Pharmacists are filling a need for the veterinarians's practice.

Please withdraw the CPG and reissue in draft form to allow for pharmacists, veterinarians and consumers to comment.

Sincerely,


Clark Gustafson, Pharm.

Cc: Mark McClellan, FDA Commissioner
Senator Diane Feinstein (D-CA)
Senator Barbara Boxer (D-CA)
Representative William Thomas (R-CA 22nd)
International Academy of Compounding Pharmacists

VILLAGE PHARMACY & COMPOUNDING CENTER

February 5, 2004

Dear Dr. Stephen Sundlof,

I provide many prescriptions for my veterinary patients every day. We help many cats and dogs when the standard available products are not helpful or are unavailable. The Compliance Policy Guide (CPG) issued by the Center for Veterinary Medicine will severely reduce the ability of pharmacists to meet the needs of these patients. I feel pharmacists need a comment-period before any final decisions are made.

Please withdraw the CPG to allow time to comment on it's provisions.

Sincerely,

Daniel A. Busichio, R.Ph.

sullivan drug store

104 MAIN STREET
PO BOX 465
LANCASTER, NH 03584
PHONE (603) 788-2751
TOLL FREE 1-800-442-4606

Sen. Sununu
I wanted to make you
aware of this recent
development. I know you've
shown interest in compounding
pharmacy in the past.
Sincerely,
DAVID ROCHEFORT

February 17, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockland, MD 20855

Dear Dr. Sundlof,

I am writing you today in response to a recent Compliance Policy Guide (CPG) issued by CVM. The CPG, *Compounding of Drugs for Use in Animals (CPG 7125.40)*, was issued in final form without allowing opportunity for comments. This, as I understand, is a violation of FDA Good Guidance Practices. There are many requirements of this CPG that are extremely problematic and should have a comment period before being put into effect. Of these, the FDA's prohibition of the use of bulk active pharmaceuticals is of most concern to me. I understand limiting or even prohibiting the use of bulk active pharmaceutical compounding for food producing animals but to extend the prohibition to pharmaceuticals used in compounding for personal pets is not only extreme but unreasonable. In my practice we often work with local veterinarians to help treat conditions common in elderly house cats. Why would the FDA want to stop this?

I ask that you withdraw the CPG and reissue it in draft form. Doing this would allow veterinarians, pharmacists, and pet owners to comment on its provisions before it is implemented.

I thank you for your attention to this matter.

Sincerely,



David Rochefort, R.Ph.

Cc: Mark McClellan, Senator Judd Gregg, Senator John E. Sununu, Representative Charlie Bass



1805 Swanson Rd
Big Stone Gap, Va 24219
(276) 523-1414 w
(276) 523-2931 fax

February 10, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am writing because I am concerned for the future of compounding. I have recently been made aware that the U.S Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) recently issued a Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients, a standard that is much more restrictive than the FDA's policies governing compounding for human patients.

I am concerned because:

1. CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices.
2. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.
3. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. There are many medications that veterinary patients need that are only provided by compounding pharmacists. If this issue stands there will be many pet owners that lose a loved or see a loved one suffer, due to lack of appropriate medication

I ask that the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Autumn S. Wells, Pharm.D., RPh

Autumn S. Wells, Pharm.D., RPh
Community Pharmacy Resident

cc: Mark McClellan, FDA Commissioner
cc: Representative Rick Boucher
cc: Senator George Allen
cc: Senator John Warner
cc: IACP

Central Pharmacy

2609 N. Duke Street, Suite 103
Durham, NC 27704
919-220-5121 FAX 919-220-6307

Bill Burch, RPh, FACA Jennifer Burch, Pharm. D. CDE Sloan Barber, Pharm. D.

October 26, 2003

Dr. Stephen Sundolf, Director
Center of Veterinary Medicing
U. S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundolf:

The FDA's prohibition in this CPG against compounding from bulk active e pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. If you have ever tried to give a cat medication by mouth you would understand the difficulty many cat owners experience. Seeing your dog have uncontrolled seizures is not a pleasant sight. Each of these examples requires compounding from bulk pharmaceuticals. These are just two simple examples of the situations that present daily to the veterinarian and compounding pharmacist. Without the ability to compound from bulk pharmaceuticals there is no solution for these owners.

CVM issued the Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. As previously stated many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. Please extend the courtesy of a comment period so you may hear why this policy needs to be revised.

Again as a courtesy the many pet owners in this country please withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and pet owners to comment on its provisions before being enforced.

Sincerely,



William Burch, RPh, FACA

Cc: Dr. Mark McCellan, Commissioner FDA
Sen. Elizabeth Dole
Sen. John Edwards
Rep. David Price

**Monfort Compounding Center, Inc.**105 North Perry Street
Lawrenceville, GA 30045Phone: 770-963-2813
FAX: 770-963-0166

October 3, 2003

Mark McClellan, MD, Ph.D.
FDA Commissioner

Dear Dr. Mark McClellan,

I thought you should receive a copy of the letter faxed to Dr. Stephen F Sundlof. This issue is of great importance to all pharmacists, veterinarians, and pet owners.

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I am writing this letter in response to the Compliance Policy Guide (CPG) that was recently issued in final form. This is in violation of the FDA Good Guidance Practices. Many of the requirements of the CPG are extremely problematic and deserve a comment period before put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is **extremely problematic**. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. While working with local veterinarians, we have saved many of our pet patients. This would not have been possible without the use of bulk drug substances that the FDA would like to ban. This is much more restrictive than compounding for humans. I do not understand why the FDA would want to put these animals in jeopardy.

I would like to request that the FDA withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians and patients to comment on its provisions before it is implemented.

Sincerely,
Laurie B. Wamack, Pharm.D.
Laurie B. Wamack, Pharm.D.Cc: Mark McClellan, FDA Commissioner
Cc: Rep. David Scott
Cc: Senator Saxby Chambliss
Cc: Senator Zell Miller

In Downtown Lawrenceville on the Historic Courthouse Square

**Monfort Compounding Center, Inc.**105 North Perry Street
Lawrenceville, GA 30045Phone: 770-963-2813
FAX: 770-963-0166

October 3, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I am writing this letter in response to the Compliance Policy Guide (CPG) that was recently issued in final form. This is in violation of the FDA Good Guidance Practices. Many of the requirements of the CPG are extremely problematic and deserve a comment period before put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is **extremely problematic**. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. While working with local veterinarians, we have saved many of our pet patients. This would not have been possible without the use of bulk drug substances that the FDA would like to ban. This is much more restrictive than compounding for humans. I do not understand why the FDA would want to put these animals in jeopardy.

I would like to request that the FDA withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians and patients to comment on its provisions before it is implemented.

Sincerely,

Laurie B. Warnack, Pharm.D.

Cc: Mark McClellan, FDA Commissioner
Cc: Rep. David Scott
Cc: Senator Saxby Chambliss
Cc: Senator Zell Miller

In Downtown Lawrenceville on the Historic Courthouse Square

Susan McCoy, Rph
117 Blackbridge Drive
Brandon, MS 39042
Phone (601) 825-7901
Mccoyrebel@aol.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

The FDA's prohibition in this Compliance Policy Guide against compounding will pose extreme problems in the medical health of our veterinary patients. It is essential that the pharmacist be allowed to compound for non-food producing animals from bulk drug substances.

If we are prohibited to compound certain palliative drugs such as potassium bromide many of our canine patients will have uncontrollable and potentially deadly seizures. This is a life threatening problem. For some of the pets, loved like family, there is no other alternative.

Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



Susan McCoy, Rph

~~cc: Mark McClellan, FDA Commissioner~~
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: IACP

David McCoy, Rph
117 Blackbridge Drive
Brandon, MS 39042
Phone (601) 825-7901
Mccoyrebel@aol.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

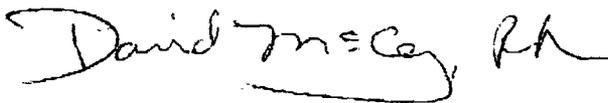
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Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



David McCoy, Rph

cc: Mark McClellan, FDA Commissioner
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: IACP

Beau Haden, Pharm D
406 Castlewoods Blvd.
Brandon, MS 39042
Phone (601) 408-6502
beauhaden@hotmail.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

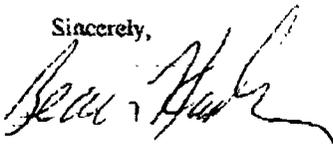
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Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



Beau Haden, Pharm D

cc: Mark McClellan, FDA Commissioner
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: IACP

Lindsey Tackett
Compounding Technician
116 Golden Estates Drive
Brandon, MS 39042
Phone (601) 825-4520
lindenlindsey@aol.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

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If we are prohibited to compound certain palliative drugs such as potassium bromide many of our canine patients will have uncontrollable and potentially deadly seizures. This is a life threatening problem. For some of the pets, loved like family, there is no other alternative.

Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



Lindsey Tackett

cc: Mark McClellan, FDA Commissioner
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: AACP

Stephanie P. Black, Pharm D
571 Acorn Lane
Brandon, MS 39047
Phone (601) 919-2638
SPaigeblack@hotmail.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

The FDA's prohibition in this Compliance Policy Guide against compounding will pose extreme problems in the medical health of our veterinary patients. It is essential that the pharmacist be allowed to compound for non-food producing animals from bulk drug substances.

If we are prohibited to compound certain palliative drugs such as potassium bromide many of our canine patients will have uncontrollable and potentially deadly seizures. This is a life threatening problem. For some of the pets, loved like family, there is no other alternative.

Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



Stephanie P. Black, Pharm D

cc: Mark McClellan, FDA Commissioner
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: IACP

Chris Couey, Rph
3954 Eastline Drive
Jackson, MS 39211
Phone (601) 368-9927
CCouey3@aol.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

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If we are prohibited to compound certain palliative drugs such as potassium bromide many of our canine patients will have uncontrollable and potentially deadly seizures. This is a life threatening problem. For some of the pets, loved like family, there is no other alternative.

Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



Chris Couey, Rph

cc: Mark McClellan, FDA Commissioner
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: IACP

Ronnie Bagwell, Rph
1042 River Oaks Drive
Flowood, MS 39232
Phone (601) 932-5444
Fax (601) 936-2166
RBagwell@martyspharmacy.com

February 5, 2004

Dear Sirs,

I have been informed that the Center for Veterinary Medicine has issued a Compliance Policy Guide in final form without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practice. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a comment period before being put into effect.

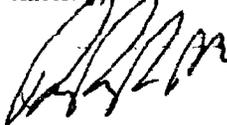
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Therefore, we are asking you to please withdraw the Compliance Policy Guide and reissue it to allow pharmacist, veterinarians, and patients to comment on it's provisions before it is implemented.

Thank you for the urgent reconsideration in this matter.

Sincerely,



Ronnie Bagwell, Rph

cc: Mark McClellan, FDA Commissioner
cc: Trent Lott, Senator
cc: Thad Cochran, Senator
cc: Chip Pickering, Representative
cc: IACP

B. RANDALL BRYANT, JR.

February 23, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

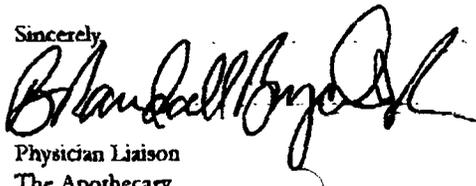
The U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) recently issued a Compliance Policy Guideline (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients, a standard that is much more restrictive than FDA's policies governing compounding for human patients.

CVM issued this Compliance Policy Guideline (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Every day in our pharmacy, we help animals receive vital care they need by individualizing doses and dosage forms to suit their size and species. Because manufacturers rarely take the time and expense to make available appropriate size and strengths available for the hundreds of different species, many animals, including pets and zoo animals, would not receive appropriate medical attention. Our society enjoys the companionship of animals, and to deprive them of medical attention is a disgrace.

I am asking FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and animal owners to comment on its provisions before it is implemented.

Sincerely,



Physician Liaison
The Apothecary

cc: Mark McClellan, FDA Commissioner
cc: Senator John Warner
cc: Senator George Allen
cc: Representative Bob Goodlatte
cc: International Academy of Compounding Pharmacists



March 4, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

The CMV issued a Compliance Policy Guide (CPG) in final form without feedback. The CPG content needs comments and feedback prior to the CPG being put into effect. The most disturbing requirement in the CPG prohibits compounding from bulk drug substance. The veterinarians in this country have a huge need for compounded medications. Pharmacists should be allowed to compound from bulk drug substances.

Please withdraw the CPG and listen to the veterinarians and pharmacists.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Beaty MD".

Barbara Beaty
Vice President

cc: Mark McClellan, FDA Commissioner
Senator Dianne Feinstein (D-CA)
Senator Barbara Boxer (D-CA)
Representative William Thomas (R-CA 22nd)
International Academy of Compounding Pharmacists



March 1, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

The CMV issued a Compliance Policy Guide (CPG) in final form without feedback. The CPG content needs comments and feedback prior to the CPG being put into effect. The most disturbing requirement in the CPG prohibits compounding from bulk drug substance. The veterinarians in this country have a huge need for compounded medications. Pharmacists should be allowed to compound from bulk drug substances.

Please withdraw the CPG and listen to the veterinarians and pharmacists.

Sincerely,


Bill Redman
Vice President of Marketing and Sales

cc: Mark McClellan, FDA Commissioner
Senator Dianne Feinstein (D-CA)
Senator Barbara Boxer (D-CA)
Representative William Thomas (R-CA 22nd)
International Academy of Compounding Pharmacists

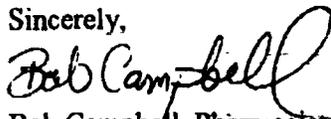
February 24, 2004

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

The recent Compliance Policy Guide issued by the Center for Veterinary Medicine regarding the use of bulk compounds for non-food animal compounding will be very problematic. With the continued exodus of major manufacturers from the veterinary market, this restriction will make the delivery of humane care to animals by veterinarians and pharmacists very difficult. It also seems the issuance of this Policy Guide without public comment is in direct conflict with the FDA Good Guidance Practices. Please withdraw this Policy Guide and allow for public comment. The public and those caring for animals deserve the chance to express their concerns and provide some rational thought on the subject.

Sincerely,



Bob Campbell, Pharmacist

cc: Mark McClellan, FDA Commissioner
Senator Dianne Feinstein (D-CA)
Senator Barbara Boxer (D-CA)
Representative William Thomas (R-CA 22nd)
International Academy of Compounding Pharmacists

706 3rd Street
Langdon, ND 58249
701-256-3330
888-757-2144
Fax: 701-256-5720

Langdon Community Drug

March 3, 2004

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

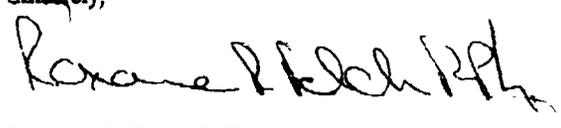
I am writing in response to the recent Veterinary Compliance Policy Guide that was issued. As a Compounding Pharmacist and concerned citizen I ask that the FDA withdraw the Vet CPG and reissue it in draft form.

CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,



Roxanne R. Felch, R. Ph.
Compounding Pharmacist

Cc: Mark McClellan, FDA Commissioner
Dr. Michael Chaddock, Director of AVMA's Government Relations
Senator Kent Conrad
Senator Byron Dorgan
Congressman Earl Pomeroy
IACP

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1907 HARRISON AVENUE N.W.
OLYMPIA, WA 98502
PHONE: (360) 709-9999
E-MAIL: makeitup@comcast.net
FAX# (360) 705-2869
Web Site: www.DeGarmo.meta-chealth.com

March 16, 2004

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am a compounding pharmacist who is very concerned with the guidelines issued by the CVM. It does not allow the opportunity for us pharmacists to comment which is in violation of FDA Good Guidance Practices. Many requirements of this CPG are very problematic and a comment period should be done before putting this into place.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,



Richard DeGarmo R.Ph.

Cc: Mark McClellan, FDA Commissioner
Cc: Senator Patty Murray
Cc: Senator Maria Cantwell
Cc: Congressman Brian Baird
Cc: IACP

DON'S
PHARMACY

501 Ralston St.
Reno, NV 89503

(775) 329-1775
800-525-9119

FAX (775) 329-6716

March 20, 2004

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Re: FDA Vet CPG Response

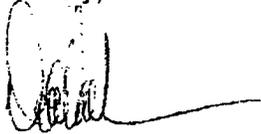
Dear Dr. Sundlof:

I am writing to express my concern for the Compliance Policy Guide (CPG). CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of the is CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,



David A. Vasenden, RPh
(775)329-2000/ (775)329-6716 fax
david@donspharmacy.com

cc: Mark McClellan, FDA Commissioner
Senator Harry Reid
Senator John Ensign
Representative James Gibbons
IACP

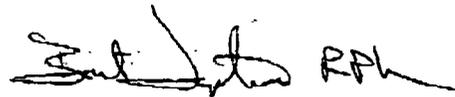
Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dr. Stephen Sundlof,

I am writing in response to the Center for Veterinary Medicine's issued Compliance Policy Guide without allowing an opportunity for comments. There are many requirements of the CPG that need to be further addressed.

The FDA's ban on compounding from bulk active pharmaceuticals for non-food producing animals may lead to a major veterinary emergency. Since many pharmaceutical companies are discontinuing a wide range of medications, it is leaving a great void to fill for the veterinarian in order to care for their patients. Without a compounding pharmacist, many animals will be unable to be treated. This may lead to many animals to be inadequately treated leading to prolonged disease, pain, and unnecessary suffering. We compound for humans using bulk drug substances and see great results that can't be met elsewhere due to large pharmaceutical companies not seeing a huge profit margin in the medications or phasing out their older drugs.

I respectfully ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, vets, and patients to comment on its provisions before it is implemented.



Bart Tipton RPh

Optimal Compounding Pharmacy
2000 Truxtun Ave.
Bakersfield, Ca 93301
(661) 716-2673

cc: Mark McClellan, FDA Commissioner; cc: Dianne Feinstein Sen; cc: Barbara Boxer Sen.; cc: Bill Thomas Rep.; cc: IACP.

Carol Lee Freedman
302 Lark Drive Newark, DE 19713

Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

December 3, 2003

Dear Dr. Sundlof,

I am an employee of a pharmacy that compounds prescriptions for animals. I want to comment on the recent revision to the Compliance Policy Guide 7125.40, section 608.400, that was initiated by the FDA Center for Veterinary Medicine. I believe this directive will have many negative repercussions for animal patients, clients, and veterinarians.

On a daily basis we interact with people who cannot thank us enough for the service we offer. That service is customizing their pet's medication into the appropriate dose for the animal's size and into a form the animal will readily take. Not only do we prepare capsules to fit the individual needs of the patient, we compound flavored liquids, chewable medications, and transdermal gels. In most cases we would probably be unable to provide a usable product, if we have to crush tablets to obtain the active ingredient. The use of bulk chemicals is key to preparing most of these prescriptions into a pharmaceutically elegant product that can be administered to the animal by a family member.

In addition to having their prescriptions looking, smelling, feeling, or tasting good, clients and veterinarians have to consider the financial impact of medicating animals. Compounding from commercially available products would adversely change the cost basis for almost all prescriptions. Many people are already stretched to the limit in providing medical treatment for their pets. If the price of their pet's medication soars, I am afraid people will have to reconsider purchasing their pet's prescriptions, especially maintenance drugs.

Another consideration is the fact that many drugs important to the well being of an animal are available only as bulk chemicals. Three of the more commonly used ones are potassium bromide for seizures, phenylpropanolamine for urinary incontinence, and cisapride for megacolon. These three are the flagships in the treatment of the aforementioned conditions.

Quality of life is important for humans and animals alike. By removing the ability of pharmacists and veterinarians to prepare prescriptions from bulk chemicals, the FDA may be condemning a vast number of animals to a shorter life and a more difficult existence. It will put stress on families who love their pets but will find themselves in the position of not being able to obtain the drugs their pets need, because there are no comparable commercially manufactured products. Even worse for many families, they may have to make the decision to put their pets "to sleep," if they cannot afford the compounded medications necessary to maintain health.

Please review the latest CPG, and consider the effect it will have on the multitude of families who have pets in need of one or more compounded medications. I believe veterinarians and compounding pharmacies should have the right to compound prescriptions from bulk chemicals.

Thank you,



Carol Lee Freedman

cc: Senator Joseph Biden
Senator Thomas Carper
Rep. Michael Castle
Mark McClellan, MD, Ph.D, FDA Commissioner
IACP



Professional Arts Pharmacy

Prescription Compounding Specialist

Eric Vidrine, P.D. F.A.C.A. Mandie Romero, P.D.
Germaine Robinson, R.Ph David Mayer, P.D.
Kevin LaGrange, R.Ph Lynn Darby, P.D.

November 26, 2003

Subject: Veterinary Pharmaceutical Compounding

Dear Senator or Representative:

The Center for veterinary medicine, U.S. FDA has issued a Compliance Policy Guide which threatens the pharmacists ability to formulate many medications for veterinary patients (pets).

CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented.

Respectfully,

Professional Arts Pharmacy

620 Guilbeau Rd., Ste. A

Lafayette, LA 70506

Ph 337-991-0101

Fax 337-991-9844

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

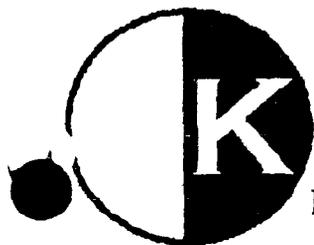
cc: ~~IACP at 281-495-0602~~

cc: Representative Chris John
cc: Representative Billy Tauzin
cc: Representative David Vitter
cc: Representative Richard Baker

cc: Senator John Breaux
cc: Senator Mary Landrieu

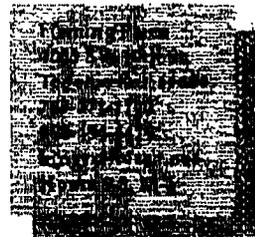
620 Guilbeau Rd., Ste. A • Lafayette, LA 70506 • Ph. 337-991-0101 1-888-237-4737 • Fx. 337-991-0151

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Wednesday, November 12, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

This letter is in reference to the recently issued Compliance Policy Guide (CPG) regarding compounding medications for animals. It is my belief this guideline threatens the ability for my pharmacy to compound medications for my veterinary patients.

My main concerns are stated below for this CPG:

- Issued in its final form without opportunity for comments, which is in direct violation of FDA Good Guidance Practices.
- Prohibits us from using bulk active pharmaceuticals to compound medications for non-food producing animals. As a result, our non-food producing patients will suffer.
Examples:
 - Three orangutans at local zoo would have died from a bacterial infection since they only accept medication mixed into a grape jelly base. The antibiotic prescribed is not commercially available in this form.
 - Dosages of commercially available prescriptions are inappropriate, i.e. use of Piroxicam for arthritic canines.

The requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. Please withdraw this CPG and reissue it in draft form to allow pharmacists, veterinarians and patient caretakers to comment on its provisions before it is implemented.

Sincerely,

Jim Schwartz, RPh.
Compounding Pharmacist

cc: Mark McClellan, FDA Commissioner ✓
Sam Brownback, Kansas Senator
Jim Ryan, Kansas Representative

KALCHEM INTERNATIONAL, INC.
224 SOUTH MAIN STREET, SUITE B
LINDSAY, OK 73052

November 7, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, Md 20855

The CVM has recently issued a Compliance Policy Guide on compounding for animals that threatens the ability of pharmacists to continue compounding medications for veterinary patients. This CPG was issued without allowing an opportunity for comments, which is in violation of FDA Good Guidance Practices. Many requirements of this CPG are problematic and deserve a comment period before being put into effect.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for veterinary patients from bulk drug substances.

Kalchem International is requesting the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.


Kohen Tabor, President

Kalchem International, Inc.
224 S. Main Street, Suite B
Lindsay, Oklahoma 73052
(405)756-8033 Fax-(405)756-2373

cc:Mark McClellan, FDA Commissioner
James Inhofe
Tom Cole
Don Nickles

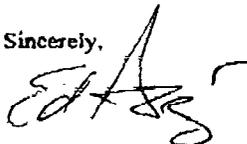
Phone 281-499-4555
Fax 281-499-7088
WWW.EDSPHARMACY.COM

November 10, 2003

Dr. Stephen Sundlof, Director
U.S. Food and Drug Administration (HFV,1)
7500 Standish Place
Rockville, MD 20855

I am concerned with many of the requirements of the Compliance Policy Guide. The prohibition of compounding from bulk pharmaceuticals for non-food producing animals is extremely problematic for myself, veterinarians, and patients. Some examples of bulk compounds include, Potassium Bromide for dogs with epilepsy, Phenylbutasone for inflammation in dogs, and Metronidazole Benzoate for many types of infections in dogs and cats. Please withdraw the Compliance Policy Guide and reissue it in draft form to allow comments from veterinarians, patients, and pharmacists.

Sincerely,



Ed Sziy, R.Ph., Owner
Ed's Pharmacy
ESZIY@houston.tx.com

cc: Mark McClellan, FDA Commissioner
cc: Sen. Kay Bailey Hutchison
cc: Sen. John Cornyn
cc: Rep. Tom DeLay
cc: IACP

Dr. Stephen Sundlof
Director Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

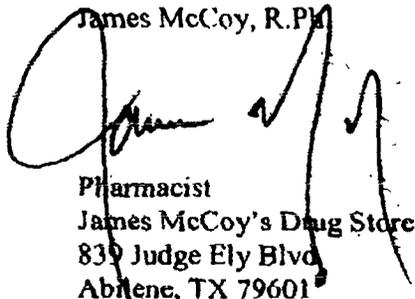
Dr. Sundlof,

I am very concerned with recent developments regarding your CPG for veterinary prescription compounding. This guide your administration has developed will do harm to many people involved such as veterinarians, pharmacists, and especially our patients. The following are concerns I have with the guidance.

1. CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.
2. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. I can cite many examples of situations in which the compounding of prescriptions from bulk drug substances for cats, dogs, and other pets have undoubtedly improved the animal's quality of life as well as the owner's.

In closing, I am asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

James McCoy, R.Ph



Pharmacist
James McCoy's Drug Store
839 Judge Ely Blvd
Arlene, TX 79601
(325) 677-2300 fax (325) 677-6800

cc: Mark McClellan, FDA Commissioner
cc: Senator John Cornyn (R-TX)
cc: Representative Charles Stenholm (D-TX 17th)
cc: International Academy of Compounding Pharmacists

Dr. Stephen Sundlof
Director Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dr. Sundlof,

I am very concerned with recent developments regarding your CPG for veterinary prescription compounding. This guide your administration has developed will do harm to many people involved such as veterinarians, pharmacists, and especially our patients. The following are concerns I have with the guidance.

1. CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA: ~~Good Guidance Practices~~. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.
2. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is ~~extremely problematic~~. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. I can cite many examples of situations in which the compounding of prescriptions from bulk drug substances for cats, dogs, and other pets have undoubtedly improved the animal's quality of life as well as the owner's.

In closing, I am asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Jason Heuerman, R.Ph., Pharm.D.



Pharmacist
James McCoy's Drug Store
839 Judge Ely Blvd.
Abilene, TX 79601
(325) 677-2300 fax (325) 677-6800

cc: Mark McClellan, FDA Commissioner
cc: Senator John Cornyn (R-TX)
cc: Representative Charles Stenholm (D-TX 17th)
cc: International Academy of Compounding Pharmacists

The Medicine Shoppe®

Stan Leggett, R.Ph.
956 North First Street, Albemarle, NC 28001
Phone (704) 983-6176 • Fax (704) 984-6513

November 5, 2003

Dear Dr. Sundlof,

I am writing you out of concern regarding the recent issuance of a Compliance Policy Guide which was put into effect without allowing comment, which I understand, is in direct violation of the FDA's Good Guidance Practices. Many areas of this CPG deserve comment as they have serious consequences.

My main area of concern is the inability to compound prescriptions for non-food producing animals from bulk drug substances. Many times there are no other sources for these pharmaceuticals as commercially prepared forms are nonexistent and must be compounded.

Please reconsider withdrawing the CPG and instead reissue it in draft form to allow veterinarian pharmacists and patient owners to comment on its provisions.

Sincerely,

Stan Leggett
Registered Pharmacist

cc:
Mark McClellan, FDA Commissioner
Senator Elizabeth Dole
Senator John Edwards
Representative Robin Hayes

What A Pharmacy Was Meant To Be®

The Medicine Shoppe®

Stan Leggett, R.Ph.
956 North First Street, Albemarle, NC 28001
Phone (704) 983-6176 • Fax (704) 984-6513

November 5, 2003

Dear Dr. Sundlot:

I am writing you out of concern regarding the recent issuance of a Compliance Policy Guide which was put into effect without allowing comment, which I understand, is in direct violation of the FDA's Good Guidance Practices. Many areas of this CPG deserve comment as they have serious consequences.

My main area of concern is the inability to compound prescriptions for non-food producing animals from bulk drug substances. Many times there are no other sources for these pharmaceuticals as commercially prepared forms are nonexistent and must be compounded.

Please reconsider withdrawing the CPG and instead reissue it in draft form to allow veterinarian pharmacists and patient owners to comment on its provisions.

Sincerely,

Lisa Kiker
Registered Pharmacist

cc:
Mark McClellan, FDA Commissioner
Senator Elizabeth Dole
Senator John Edwards
Representative Robin Hayes

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The Medicine Shoppe®

Stan Leggett, R.Ph.
956 North First Street, Albemarle, NC 28001
Phone (704) 983-6176 • Fax (704) 984-6513

November 5, 2003

Dear Dr. Sundlof,

I am writing you out of concern regarding the recent issuance of a Compliance Policy Guide which was put into effect without allowing comment, which I understand, is in direct violation of the FDA's Good Guidance Practices. Many areas of this CPG deserve comment as they have serious consequences.

My main area of concern is the inability to compound prescriptions for non-food producing animals from bulk drug substances. Many times there are no other sources for these pharmaceuticals as commercially prepared forms are nonexistent and must be compounded.

Please reconsider withdrawing the CPG and instead reissue it in draft form to allow veterinarian pharmacists and patient owners to comment on its provisions.

Sincerely,

Charles Ingram
Registered Pharmacist

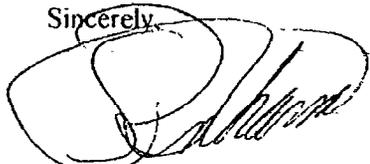
cc:
Mark McClellan, FDA Commissioner
Senator Elizabeth Dole
Senator John Edwards
Representative Robin Haycs

What A Pharmacy Was Meant To Be®

I have a "wall of pictures" of animals from dogs, cats, birds, guinea pigs, tortoises, etc that the animal's owners have brought me in appreciation of the medications that I made from their animals that would otherwise be unavailable to them according to this CPG. With bulk chemicals available, I can prepare these products in the correct dose, the best dosage form, and appropriately flavored for the target animal. The compounding pharmacist is the best equipped and education professional to prepare these medications

Please reconsider opening the CPG to a public comment period for further consideration.

Sincerely,



Steven E. Bonham Pharm. D.
Fair Oaks Pharmacy
1051 Grand Ave
Arroyo Grande, Ca 93420
805-489-4235

cc FDA Commissioner Mark McClellan
The Honorable Dianne Feinstein
The Honorable Barbara Boxer
The Honorable Lois Capps
IACP

LIGGETT COMPOUNDING PHARMACY
1053 HIGHWAY #1, PATTERSON PLAZA, PO BOX 236
TELEPHONE AND FAX 803-438-8234
YOUR HOME TOWN HEALTH AND WELLNESS CENTER

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I am very concerned about the Compliance Policy Guide concerning compounding using bulk drug substances.

CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. One example that illustrates this problem is potassium bromide for seizure disorder in dogs. Potassium bromide is available only as a bulk drug. Our local veterinarians have prescribed potassium bromide for a number of dogs when other drugs have failed to stop seizures and the seizure disorder in these dogs is now controlled. One veterinarian has her own dog on the potassium bromide.

Please withdraw the CPG and reissue it in draft form to allow for pharmacist, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Charles F. Smith R.Ph.

Charles F. Smith R.Ph.

cc: Mark McClellan, FDA Commissioner
cc: Senator Ernest Hollings
cc: Senator Lindsey Graham
cc: Representative John Spratt
cc: IACP

LIGGETT COMPOUNDING PHARMACY
1053 HIGHWAY #1, PATTERSON PLAZA, PO BOX 236, LUGOFF, SC 29078
TELEPHONE AND FAX 803-438-8234
YOUR HOME TOWN HEALTH AND WELLNESS CENTER

Dr. Stephen F Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

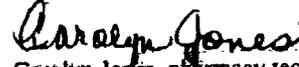
I am very concerned about the Compliance Policy Guide concerning compounding using bulk drug substances.

CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Many drugs used to compound for non-food producing animals, such as phenylpropanolamine, diethylstilbestrol, cisapride, potassium bromide, and others are available only as bulk drug substances.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,



Carolyn Jones, pharmacy technician

cc. Mark McClellan, FDA Commissioner
cc. Senator Ernest Hollings
cc. Senator Lindsey Graham
cc. Representative John Spratt
cc. IACP



IOWACARE PHARMACY
Iowa Pharmacists Caring for You.



P.O. Box 528, Nevada, Iowa 50201

Ph: 515-382-5249

Fax: 515-382-6802

FAX TRANSMISSION

DATE: 11/18/03

FAX: 281-495-0602

TO: IACP

FROM: Bonnie Sadler

NUMBER OF PAGES (including cover sheet): 18

SPECIAL INSTRUCTIONS: _____

274 signatures (pet owners & vets)

This is a confidential message intended solely for the person to whom it is addressed. If you receive this message in error, please forward to the correct person or call us. Thank you.

November 18, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am writing on behalf of NuCara Pharmacy and the patients we serve regarding the CVM's issuing of the Compliance Policy Guide (CPG) in its final form without allowing opportunity for comments. Issuing this CPG in final form without comment is in violation of the FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic, and will result in a lack of access by patients/owners to currently-prescribed medicinal formulations. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am enclosing a list of veterinarians and companion animal owners that are concerned that their pet may not be able to receive medically necessary medications, as a result of this issuance. These veterinarians and caregivers are concerned that their pets will no longer be able to receive medications that are specially compounded to ensure adequate drug delivery, such as transdermal medications dosed through the pet's ear and medications incorporated into chewable treats.

We are asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,



Bonnie Sadler
(319) 404-1348
bonnie@nucara.com

Corporate Office
1002 Sixth Street, Box 215
Nevara, IA 50201
Phone: 515-382-5249
FAX: 515-382-6802

5770 N. MoPac Expressway
Suite 104
Austin, TX 78731
Phone: 512-454-9923
FAX: 512-454-9866

1150 Fifth Street, Ste. 140
City Center, Coralville, IA 52241
Phone: 319-354-6006
FAX: 319-354-6050

209 East San Martin
Waterloo, IA 50702
Phone: 319-236-8891
FAX: 319-236-9665

cc: Mark McClellan, M.D., Ph.D., FDA Commissioner

Representative Nussle - IA

Representative Leach - IA

Representative Latham - IA

Representative Boswell - IA

Senator Harkin - IA

Senator Grassley - IA

Senator Cornyn - TX

Senator Hutchison - TX

Representative Smith - TX

Representative Doggett - TX

IACP

Dr. Michael Chaddock, Director AVMA's Government Relations Division

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 the AVMA (American Vet Medical Association).

<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. NANCY GIBSON	9635 Independence Ave	Waterloo, IA 50703
2. Jeffrey A. Egan	32283-270th St.	Shell Rock IA 50670
3. Walter	25308 Hwy 57	Parkersburg, IA 50665
4. Neddly K. Burns	708 Chestnut	Laporte, IA 50651
5. Mandys Moore	8100 Kimball Ave	Waterloo, IA 50701
6. Leige Pollock	70296 Hwy 57	Parkersburg IA 50665
7. Peter Glone	5424 Hickman St	Waterloo, IA 50703
8. Don J. [unclear]	19816 280th St	Parkersburg
9. Cindy [unclear]	19816 280th	Parkersburg
10. Kim [unclear]	519 Ankeny St.	Waterloo, IA 50703
11. Carolyn [unclear]	813 [unclear] St	Waterloo 50712
12. Karen [unclear]	Box 956 508th Ave SW	Truman IA 50676
13. Rebecca Hickok	218 N. Ellen St.	Cedar Falls, IA 50613
14. Susan J. Ward	811 Moir St	Waterloo, IA 50701
15. Fanny [unclear]	2709 Grand Blvd	Cedar Falls, IA 50613
16. Gary [unclear]	203 [unclear]	Waterloo Iowa 50701
17. Jay B. [unclear]	501 CORNWALL AVE.	WATERLOO, IA 50702
18. Roman [unclear]	4715. DUCSADA Ave	C. Falls 50613
19. Bob [unclear]	1205 Country [unclear]	Waterloo, 50677
20. [unclear] Madgen	13682 X Ave	Cedar Falls
21. [unclear] [unclear]	3322 [unclear] Dr	Waterloo
22. [unclear] [unclear]	4232 Wells Ave.	Waterloo, Ia 50703
23. [unclear] [unclear]	418 Dixie Circle	Evansdale IA 50707
24. [unclear] [unclear]	1545 [unclear]	Waterloo IA 50701
25. [unclear] [unclear]	1071 W. Elk Run Rd	Waterloo 50703
Merna Slack	113 [unclear]	Waterloo 50703
[unclear] [unclear]	2855 [unclear]	Waterloo 50702
Jamie Steele	301 Upper Ridge St	Waterloo IA 50709
	Keimbeck	

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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Oliver Boehm</u>	<u>721 E. Ridgeway Ave</u>	<u>Waterloo Ia 50702</u>
2. <u>Jay Jan</u>	<u>2508 5th Ave</u>	<u>Cluver, IA 52217</u>
3. <u>Betsy Binklund</u>	<u>708 Reber Xve</u>	<u>Waterloo, IA 50701</u>
4. <u>Ben Foltz</u>	<u>718 W 7th St.</u>	<u>Waterloo, Ia 50702</u>
5. <u>Kelli Headington</u>	<u>1200 Kaplan Dr.</u>	<u>Waterloo IA 50702</u>
6. <u>Arnell Schira</u>	<u>844 Doherty</u>	<u>Quincy Ia 50648</u>
7. <u>Andrew Lake</u>	<u>1112 State St</u>	<u>Eden Falls IA 50613</u>
8. <u>Ken [unclear]</u>	<u>813 Belle St</u>	<u>Waterloo IA</u>
9. <u>Ben [unclear]</u>	<u>1604 Oriole</u>	<u>Waterloo IA 50701</u>
10. <u>Raymond E. [unclear]</u>	<u>2022 Cypress Ave</u>	<u>Cedar Falls, IA 50613</u>
11. <u>Dev Hunter</u>	<u>1311 Randolph</u>	<u>Waterloo Ia 02</u>
12. <u>Lori Guimond</u>	<u>PO BOX 727</u>	<u>Cedar Falls, IA</u>
13. <u>Carol Hazel</u>	<u>PO BOX 105</u>	<u>Raymond Ia 50667</u>
14. <u>Kathleen [unclear]</u>	<u>516 Olive St E</u>	<u>Cedar Falls IA 50613</u>
15. <u>[unclear]</u>	<u>1621 Partridge</u>	<u>Waterloo, Ia 50701</u>
16. <u>[unclear]</u>	<u>211 2nd Ave NE</u>	<u>Wacama Ia</u>
17. <u>Hildegard [unclear]</u>	<u>1106 ORA DR</u>	<u>Waterloo IA 50701</u>
18. <u>Cheryl Becroft</u>	<u>105 Westridge Ct.</u>	<u>LaPorte City, IA 50651</u>
19. <u>Pamela [unclear]</u>	<u>2311 Green Creek Rd.</u>	<u>Cedar Falls 50613</u>
20. <u>[unclear]</u>	<u>2711 W. 3rd St</u>	<u>Cedar Falls 50613</u>
21. <u>Thomas J. [unclear]</u>	<u>3003 WINTER RIDGE LANE</u>	<u>Cedar Falls IA 50613</u>
22. <u>Edwin Walter</u>	<u>214 Main</u>	<u>Conrot, Ia. 50621</u>
23. <u>Dan Guter</u>	<u>121 Pershing Rd</u>	<u>Waterloo Ia 50701</u>
24. <u>Lindy Strahman</u>	<u>427 Norris Ct</u>	<u>Waterloo IA 50701</u>
25. <u>Pat Werring</u>	<u>2623 Idaho St.</u>	<u>Waterloo IA 50703</u>

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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Peggy Davis</u>	<u>702 Lorraine</u>	<u>Waterloo IA 50702</u>
2. <u>Jeremy Strickman</u>	<u>427 Norris Ct</u>	<u>Waterloo IA 50701</u>
3. <u>Kelly Simon</u>	<u>25508 Hwy 57</u>	<u>Parkersburg IA 50465</u>
4. <u>Theresa Blom</u>	<u>31856 270th St</u>	<u>Reinbeck IA 50665</u>
5. <u>Lee Thurmond</u>	<u>1550 E Mitchell Ave</u>	<u>Waterloo, IA 50702</u>
6. <u>Mariene Shea</u>	<u>4715 Quenada Ave</u>	<u>Cedar Falls, IA 50613</u>
7. <u>Carlo Simon</u>	<u>419 Heritage Rd</u>	<u>Cedar Falls IA 50613</u>
8. <u>Sharon Messer</u>	<u>5434 Teem Rd</u>	<u>FAIRBANK IOWA 50629</u>
9. <u>[Signature]</u>	<u>17116 Herold Ave</u>	<u>Waterloo, IA 50702</u>
10. <u>Don Moore</u>	<u>8100 KIMBALL AVE</u>	<u>WATERLOO IA 50701</u>
11. <u>Lee Folbert</u>	<u>17849 220 St</u>	<u>Altamont, Ia 50602</u>
12. <u>Sandra Zimmerman</u>	<u>2611 W 8th</u>	<u>Waterloo, Ia 50702</u>
13. <u>Jay Cole</u>	<u>503 Grand Ave</u>	<u>Des Moines, Ia 50326</u>
14. <u>Reena Lesvitt</u>	<u>4832 W. Bennington</u>	<u>Cedar Falls, Ia. 50613</u>
15. <u>Dakota Thyle</u>	<u>1014 Park Ave</u>	<u>Waterloo Ia 50701</u>
16. <u>Donald Kopp</u>	<u>74 River Ridge Rd</u>	<u>Cedar Falls Ia 50613</u>
17. <u>James J. Biern</u>	<u>621 OREGON</u>	<u>WATERLOO, IOWA 50702</u>
18. <u>Marsha Becker</u>	<u>302 Walnut</u>	<u>Cornell Ia 50621</u>
19. <u>Mike M. Mabe</u>	<u>415 Walnut St</u>	<u>Cedar Falls, IA 50613</u>
20. <u>Don M. Gomer</u>	<u>1412 Parker St.</u>	<u>Cedar Falls, IA 50613</u>
21. <u>Jan Hoffmeyer</u>	<u>406 Wilson St</u>	<u>Decorah, Ia 52224</u>
22. <u>Kildred Carson</u>		
23. <u>Barbara Meyer</u>	<u>813 Wesleyan Dr</u>	<u>Waterloo, Ia 50702</u>
24. <u>Thomas Hobbs</u>	<u>225 W. Riponway</u>	<u>Waterloo, Ia</u>
25. <u>Shee Garsden</u>	<u>280 Derbyside Rd.</u>	<u>Waterloo, IA 50701</u>

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1. <u>Bob Hunter</u>	<u>1311 Randolph</u>	<u>W'loo Ia 50702</u>
2. <u>Helan M. Nichols</u>	<u>13340 Indian Creek Rd.</u>	<u>Jeppia Ia 50648</u>
3. <u>Maria Ann</u>	<u>3534 Twinkberry Dr.</u>	<u>Waterloo Ia 50701</u>
4. <u>T. J. K. K. K.</u>	<u>1576 W. Co Rd</u>	<u>Waterloo Ia 50707</u>
5. <u>John A. P.</u>	<u>2020 Wembley Rd</u>	<u>Waterloo IA 50701</u>
6. <u>Terry C. P.</u>	<u>1731 Cottage Dr</u>	<u>Waterloo IA 50707</u>
7. <u>Frank B. G.</u>	<u>169 BECKSWIRE</u>	<u>Waterloo, Iowa</u>
8. <u>Jim D.</u>		<u>Cedar Falls</u>
9. <u>Bob Hunter</u>		
10. <u>Sandi W.</u>	<u>1211 5TH AVE SE</u>	<u>Waverly, Ia 50177</u>
11. <u>Henry P.</u>	<u>2213 W. 8TH ST.</u>	<u>CEGAR FALLS IA 50613</u>
12. <u>Henry P.</u>	<u>Dupont Rd #1</u>	<u>Dupont IA 52224</u>
13. <u>Ernie B. E.</u>	<u>1014 Melrose Dr.</u>	<u>CF IA 50613</u>
14. <u>Wade S.</u>	<u>1674 Oakwood</u>	<u>W'loo, IA 50703</u>
15. <u>Aguelina E.</u>	<u>1305 Painters Dr.</u>	<u>CF IA 50613</u>
16. <u>Jinda J.</u>	<u>7392 Central Ave</u>	<u>CF Iowa 50613</u>
17. <u>Anna W.</u>	<u>105 W 2nd St</u>	<u>Gladbrook, Iowa 50625</u>
18. <u>Tom Adams</u>	<u>217 Main St.</u>	<u>Waterloo IA 50701</u>
19. <u>Justin A.</u>	<u>125 Barrington Dr.</u>	<u>Waterloo IA 50701</u>
20. <u>Susan A.</u>	<u>23539 310th St</u>	<u>Piburg Ia 50665</u>
21. <u>Marilyn G.</u>	<u>442 Olympic Dr.</u>	<u>Waterloo IA 50701</u>
22. <u>Kim S.</u>	<u>408 Hartman</u>	<u>Waterloo Ia 50701</u>
23. <u>Marilyn A.</u>	<u>1409 E. Shawler St</u>	<u>Waterloo Ia 50701</u>
24. <u>Tom H.</u>	<u>23508 McChave Rd</u>	<u>LPC IA 50651</u>
25. <u>Mona Smith</u>	<u>1901 Orchard Dr.</u>	<u>Cedar Falls 50613</u>

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1. <u>Ronett Berry</u>	<u>1536 W Donald St</u>	<u>W 100 IA 50703</u>
2. <u>Sharon M. Hildman</u>	<u>1734 Dakota Dr.</u>	<u>Waterloo IA 50701</u>
3. <u>Marlene Shewe</u>	<u>509 3rd St. S.E.</u>	<u>Waverly IA 50677</u>
4. <u>Shirley J. Schum</u>	<u>23539 310th St</u>	<u>Parkersburg Ia 50605</u>
5. <u>Craig Herman</u>	<u>415 Indiana St</u>	<u>Waterloo IA 50702</u>
6. <u>Sharon Herman</u>	<u>2349 Adams Rd</u>	<u>Waterloo IA 50701</u>
7. <u>Janice Decker</u>	<u>8912 W 12th St.</u>	<u>Cedar Falls IA 50613</u>
8. <u>Bonnie Sadler</u>	<u>1012 E Donald</u>	<u>Waverly Ia 50677</u>
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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Joel Duran</u>	<u>2917 Meadow Cir NE</u>	<u>Jesse City, Ia 52240</u>
2. <u>Aden Oberhol</u>	<u>713 Manor Dr</u>	<u>Iowa City, IA 52248</u>
3. <u>Joan Thruft</u>	<u>3329 Robert Rd</u>	<u>Iowa City, IA 52240</u>
4. <u>Lyda Tomlin</u>	<u>1909 Glendale Rd</u>	<u>Boona City, IA</u>
5. <u>Alma Kelso</u>	<u>924 Sunset St.</u>	<u>Iowa City 52245</u>
6. <u>Bob J. Jones</u>	<u>707 River St.</u>	<u>Iowa City, IA 52246</u>
7. <u>Janet Ashman</u>	<u>903 Fifth Ave</u>	<u>Iowa City, IA 52240</u>
8. <u>Kimberly Schauer</u>	<u>1415 McKinley Place</u>	<u>Iowa City, IA 52246</u>
9. <u>Hilma Kuehn</u>	<u>PO Box 1223</u>	<u>Iowa City IA 52248</u>
10. <u>Kevin Ann Fullenk</u>	<u>649 Railroad St.</u>	<u>North Liberty, IA 52317</u>
11. <u>Donna Uebing</u>	<u>1380 S. University</u>	<u>I.C. 52240</u>
12. <u>Marilyn Hartling</u>	<u>1540 Prairie du Chien</u>	<u>Iowa City, IA 52245</u>
13. <u>Bill Madden</u>	<u>1831 Timber Hills Dr.</u>	<u>Coraville 52241</u>
14. <u>Margaret Cretzinger</u>	<u>1129 Howell St</u>	<u>Iowa City 52240</u>
15. <u>Wally Brennan</u>	<u>1125 St. Andrews Dr</u>	<u>North Liberty, Ia 52317</u>
16. <u>[Signature]</u>	<u>3065 27th St</u>	<u>Williamsburg IA 52361</u>
17. <u>Jan Weber</u>	<u>340 Oak St Riverside</u>	<u>Riverside Ia 52327</u>
18. <u>Carolee Dieterle</u>	<u>727 Walnut St.</u>	<u>Iowa City, Ia. 52240</u>
19. <u>Jane Helms</u>	<u>1250 DEERFIELD DRIVE</u>	<u>NORTH LIBERTY, IA 52317</u>
20. <u>Alma James</u>	<u>2235 Shropshire Cir</u>	<u>Coraville IA 52241</u>
21. <u>Susan Roth</u>	<u>1607 Morningside</u>	<u>Iowa City, IA 52245</u>
22. <u>Janet Jones</u>	<u>1107 Lincoln Dr</u>	<u>Windsor Ia 52256</u>
23. <u>Ann Murphy</u>	<u>4671 Sharon Court Rd</u>	<u>Iowa City IA 52240</u>
24. <u>Cherie Blair</u>	<u>631 Bernard Street</u>	<u>Iowa City, Ia 52248</u>
25. <u>Cathy Busch</u>	<u>2996 Eagle Ave NW</u>	<u>Oxford IA 52322</u>

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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Jammi Whitton</u>	<u>1107 Millberry Ave</u>	<u>Muscogatae IA 52241</u>
2. <u>Regina M. Miller</u>	<u>970 Applewood Ct Apt 2</u>	<u>Coralville, IA 52241</u>
3. <u>Greg Stolpe</u>	<u>Box 1161</u>	<u>Williamsburg IA 50361</u>
4. <u>Lessa Mitchell</u>	<u>107 5th St. Coralville, Ia</u>	<u>52241</u>
5. <u>Virginia K. Peirce</u>	<u>19231 Irish Ridge Rd.</u>	<u>Sperry, IA 52650</u>
6. <u>Ana Bessy</u>	<u>3005 Radcliffe Ave.</u>	<u>Iowa City, IA 52245</u>
7. <u>Margaret Cooper</u>	<u>2438 Walden Court</u>	<u>Iowa City, Ia 52246</u>
8. <u>Bradley K. Miller</u>	<u>1654 Ridge Rd</u>	<u>Iowa City, IA 52245</u>
9. <u>Douglas R. Faithand</u>	<u>4508 SE OAK CREST HILL RD</u>	<u>Iowa City, Ia 52240</u>
10. <u>Sonja L. Faithand</u>	<u>4508 SE Oak Crest Hill rd</u>	<u>Iowa City, Ia 52240</u>
11. <u>Constance Magee</u>	<u>910 Forest Edge Drive.</u>	<u>Coralville, Ia 52241</u>
12. <u>Kim Williams</u>	<u>PO Box 5243</u>	<u>Coralville Ia 52241</u>
13. <u>Beth K. Miller</u>	<u>30887 57th St</u>	<u>Charita Ia 52242</u>
14. <u>Deborah Miller</u>	<u>21 Riverwood Dr NE</u>	<u>Iowa City IA 52240</u>
15. <u>Larry Deal</u>	<u>1049 VINE AVE, RIVERSIDE</u>	<u>IA 52327</u>
16. <u>Dr. Lynn</u>	<u>758 Westwinds Dr</u>	<u>Iowa City, Ia 52246</u>
17. <u>Amy K. Truwein</u>	<u>606 1/2 Church St.</u>	<u>Iowa City IA 52245</u>
18. <u>Helen Rice</u>	<u>995 Applewood Ct #2</u>	<u>Coralville IA 52241</u>
19. <u>Colleen P. Strick</u>	<u>9 Apollo Place</u>	<u>Iowa City, IA 52240</u>
20. <u>D.W. Miller</u>	<u>15 Lakewood Dr N.E.</u>	<u>Iowa City, Ia 52241</u>
21. <u>Betty Beinfeld</u>	<u>148 Holiday Ridge Rd</u>	<u>N.L. City, Ia 52817</u>
22. <u>Bob Miller</u>	<u>1735 240th St</u>	<u>Williamsburg, IA</u>
23. <u>Pamela KALLAP</u>	<u>1035 RIVER ST.</u>	<u>IOWA CITY, IA 52246</u>
24. <u>Matthew Cabot</u>	<u>2876 315th St</u>	<u>Coralville, IA 52241</u>
25. <u>Melanie Christophers</u>	<u>224 N. 10th St</u>	<u>West Branch, Ia 52358</u>

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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Tara Bowler</u>	<u>3272 Midway Rd</u>	<u>Marion Iowa 52302</u>
2. <u>Dorothy Smith</u>	<u>2801 Hwy 6 E #289</u>	<u>Jowa City, Iowa 52240</u>
3. <u>Robert Schopf</u>	<u>342 S. Dodge</u>	<u>Jowa City IA 52240</u>
4. <u>Ann Koch</u>	<u>10015 Park FF</u>	<u>Jowa 52255</u>
5. <u>Judy Krosch</u>	<u>92 Wrexham Dr.</u>	<u>Jowa City IA 52246</u>
6. <u>Thermaine Berach</u>	<u>1511 E. College St</u>	<u>Jowa City, IA 52245</u>
7. <u>Lynn Rose</u>	<u>1816 Muscatine Ave</u>	<u>Jowa City IA 52240</u>
8. <u>Brad Johnson</u>	<u>1651 Ridge Rd</u>	<u>Jowa City, IA 52245</u>
9. <u>Sara Ann Schubert</u>	<u>2105 I St.</u>	<u>Jowa City, IA 52240</u>
10. <u>Phil C. Cline</u>	<u>804 Fanchief St</u>	<u>Jowa City, IA 52240</u>
11. <u>Chad Dierin</u>	<u>4033 Richard Rd NE</u>	<u>Cedar Rapids, IA 52402</u>
12. <u>Janet Kelleher</u>	<u>1946 Garret Dr.</u>	<u>Coralville, Ia</u>
13. <u>Cary & Pruitt</u>	<u>5650 47th St NE</u>	<u>Cedar Rapids IA 52411</u>
14. <u>Alvin Lewis</u>	<u>2400 A - Ridge Dr.</u>	<u>Coralville, IA 52241</u>
15. <u>Ann C. Clark</u>	<u>2101 70th Ave #2</u>	<u>Coralville IA 52241</u>
16. <u>Barbara Eckstein</u>	<u>1020 Church St</u>	<u>Jowa City IA 52245</u>
17. <u>Karen Kuentzer</u>	<u>15989 City Rd 6-40</u>	<u>Col Grl Ia 52738</u>
18. <u>Barbara Heck</u>	<u>1532 E. Washington</u>	<u>Jowa City, Ia 52240</u>
19. <u>Priscilla Price</u>	<u>28 Jema Ct</u>	<u>Jowa City, IA 52246</u>
20. <u>Debra King</u>	<u>PO Box 190 - 26 W Bond</u>	<u>North English, Ia 52316</u>
21. <u>Sharon Miller</u>	<u>1417 Ash St</u>	<u>Jowa City 52240</u>
22. <u>Kelly Foster</u>	<u>2025 Little Creek Ln</u>	<u>Jowa City IA 52246</u>
23. <u>Rozemary Kraack</u>	<u>3057 Wayne Ave #53</u>	<u>Jowa City IA 52240</u>
24. <u>Sandra Jones</u>	<u>2624 Newport Pkwy</u>	<u>Jowa City, IA 52240</u>
25. <u>Bro. M. Adams</u>	<u>1831 timber field Dr</u>	<u>Coralville, Ia 52241</u>

I support the practice of compounding from bulk drug substances for animals. The use of bulk substances is acceptable for human compounding per the FDA. Some medications for animal use are only available as bulk chemicals. Eliminating the use of bulk chemicals will affect my ability to provide appropriate treatment options.

Your signature will be forwarded to the FDA and the AVMA (American Vet Medical Association).

<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Mildred Ste</u>	<u>Iowa City</u>	<u>Iowa City IA 52245</u>
2. <u>Stephanie Ball</u>	<u>1742 Lake Front Dr.</u>	<u>Solon IA 52333</u>
3. <u>Paula Kufus</u>	<u>13304 260th St.</u>	<u>Radcliffe IA 50222</u>
4. <u>Sheeli Lipt</u>	<u>2894 190th St</u>	<u>Mason IA 50565</u>
5. <u>Joy Lipt</u>	<u>217 Orange Ave</u>	<u>Ames IA 50010</u>
6. <u>Christina M. Moly</u>	<u>1103 W Maus</u>	<u>Iowa City IA 52242</u>
7. <u>Kinda Kandi DVM</u>	<u>364 Heather Ct</u>	<u>Eu Claire WI 54701</u>
8. <u>Elizabeth J. Thatcher DVM</u>	<u>6301 Hickman Rd.</u>	<u>Des Moines IA 50322</u>
9. <u>Katie Morse</u>	<u>6301 Hickman</u>	<u>DSM IA 50322</u>
10. <u>William Weber</u>	<u>Iowa City</u>	<u>Iowa City IA 52240</u>
11. <u>Mary Hanks</u>	<u>Atascuilla</u>	<u>GA 30476-7548</u>
12. <u>Lisa S. Deppa DVM</u>	<u>James Lee Chemical Corp</u>	<u>Jewell IA 50130</u>
13. <u>Rep. Marcie Frewet</u>	<u>P.O. 324; 3655 450 Ave.</u>	<u>Emmetsburg IA 50536</u>
14. <u>William M. Jarrow</u>	<u>3835 430th Ave</u>	<u>Emmetsburg IA 50536</u>
15. <u>Doug Hartman</u>	<u>110R</u>	<u>Iowa City</u>
16. <u>L. T. Zech</u>	<u>400 Jefferson</u>	<u>Waterloo IA 50701</u>
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**Your signature will be forwarded to the FDA and
the AVMA (American Vet Medical Association).**

<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Lavvi Jenvisch</u>	<u>808 S. 7th Av.</u>	<u>Lowry City, IA 52240</u>
2. <u>Eugenia T. M. See</u>	<u>970 Applewood Ct Apt 2</u>	<u>Coralville, IA 52241</u>
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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. Rachel Yoder	11633 Angle Rd. SW	Kalona, IA 52247
2. David H. Sedy, DVM	305 5th St, P.O. Box 610	Kalona, IA 52247
3. Mary J. G. Nelson	705 Hwy 1 W	Iowa City, IA 52246
4. Sandra Deussen	"	"
5. Barb O'Donnell	"	"
6. Todd Deussen, DVM	23118 Hwy 92 E	Okaloosa, Ia. 52577
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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Cherise Reese</u>	<u>1905 Rampart Circle</u>	<u>Austin, TX 78727</u>
2. <u>Alix Knauth</u>	<u>103 W. Skyview Rd.</u>	<u>Austin, TX 78752</u>
3. <u>Kris Kemp</u>	<u>1802 Portlow Drive</u>	<u>Austin TX 78757</u>
4. <u>Amelia Roberts</u>	<u>Steel Woodrow Ave #10</u>	<u>Austin, TX 78756</u>
5. <u>Robert Pender</u>	<u>5104 W. Wanda Ave. #10</u>	<u>Austin, TX 78784</u>
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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>Daryl Neams DVM</u>	<u>1200 W. Pecan St</u>	<u>Pflugerville, TX 78660</u> ²⁵¹⁻²²⁷⁴
2. <u>Angie B Campbell DVM</u>	<u>2801 Hidden Forest</u>	<u>McKinney, TX 75070</u>
3. <u>Jan Smith</u>	<u>4628 W Plano Pkwy</u>	<u>Plano, TX 75093</u>
4. <u>Jan Smith</u>	<u>9849 FM 156 S.</u>	<u>Justin, TX 76247</u>
5. <u>Susan Smith</u>	<u>9849 FM 156 South</u>	<u>Justin, TX 76247</u>
6. <u>Leslie L. Monrond DVM</u>	<u>2201 W 7th</u>	<u>Clouis, NM 88101</u>
7. <u>JENNIFER Abel</u>	<u>P.O. Box 611</u>	<u>SAN MARCO TX 78682</u>
8. <u>Adele Sperting</u>	<u>10050 Great Hills #1005</u>	<u>Austin TX 78759</u>
9. <u>Margaret Shupard</u>	<u>902 E. 53rd St</u>	<u>Austin TX 78751</u>
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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. <u>[Signature]</u>	13021 Legendale Dr. #835	Austin, TX 78707
2. <u>Verina Kolenda</u>	7203 Anaque Dr	Austin, TX 78750
3. <u>[Signature]</u>	11215 [unclear] Blvd	Austin, TX 78759
4. <u>Laurie Dancy</u>	801 Glen Rd	Austin, TX 78753
5. <u>Sarah Springs</u>	5807 Link Ave	Austin, TX 78752
6. <u>[Signature]</u>	2331 Cypress Pt East	Austin, TX 78746
7. <u>Susan Blount</u>	3902 Bonnell Dr	Austin, TX 78731
8. <u>Nancy Gorman</u>	4200 Waterford Dr	Austin, TX 78731
9. <u>Judith Brown</u>	10051 Ideas West Way	Round Rock, TX 78664
10. <u>Susan Lehman</u>	4503 Patsy Pkwy	Austin, TX 78744
11. <u>Leanne Neil</u>	2308 Greenleaf Pkwy	Austin, Tex. 78757
12. <u>Annelle Dunlop</u>	6400 La Carrae Ln.	Austin, TX 78749
13. <u>Anne Gault</u>	6401 Birdie Ln	78745
14. <u>Paul F. Freese</u>	6815 Willamette Drive	Austin, TX 78723
15. <u>Debbie Layne</u>	2705 Melba Pkwy	Cedar Park, TX 78613
16. <u>[Signature]</u>	105 Cunningham Dr	Austin, TX 78753
17. <u>[Signature]</u>	7504 Chimney corner	Austin, TX 78731
18. <u>Michael Johnson</u>	5205 Woodview	Austin, TX 78756
19. <u>[Signature]</u>	2403 Spring Creek	Austin 78704
20. <u>[Signature]</u>	3300 French Place	Austin, TX 78722
21. <u>Jay Denthorne</u>	701 RR 920	Leander, Tex 78644
22. <u>[Signature]</u>	574 Perching Ave S. 200	San Antonio, TX 78209
23. <u>[Signature]</u>	5609 Shady Oak Ct	Austin, TX 78756
24. <u>[Signature]</u>	7320 LAKE CHARLES DR	Austin, TX 78744
25. <u>Yara Bruner</u>	12004 Rosethorn Dr	Austin, TX 78758

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<u>Name</u>	<u>Address</u>	<u>City/State/Zip</u>
1. Dr. Kimberly K. Weiss	22116 Forest Rd.	Edmond OK 73003
2. Marcus J. Dutton	913A Roberts Ct off	River Oaks TX 76114
3. Jackie Marshall	8919 Wayburn Circle	Harbor TX 77088
4. Dr. Forgett	6302 W. Persimmon	Flushing ME 48433
5. Angel V.	702 Bay Area Blvd	League City TX 77573
6. Michael D. Quinn DVM	10788 Grant Rd	Houston TX 77070
7. Chen Nelson	1806 McCright	Asstrop CA 91220
8. G. R. D. DVM	1228 E. YEAGUA	Groesbeck TX 76642
9. Neil D.	119 N. Bill	Cedar Park TX 78613
10. Tennell W. D.	3325 Phoenix Dr	Ft Worth TX 76116
11. Dr. D. D. DVM	3905 Liberty Hwy	Anderson SC 29621
12. Dr. D. D. DVM	715 W. Belknap	Bellevue TX 76858
13. Dr. D. D. DVM	14067 Pennell Lane	Farmers Branch TX 75234
14. Dr. D. D.	801 E. I. 30	Richardson TX 75080
15. Erin M. C. C.	905 S. Country	Crocker TX 76036
16. MARY R. D.	905 S. Country	Crocker TX 76036
17. Dr. D. D.	3310 Wolforth Dr.	Grand Prairie TX 75052
18. Dr. D. D.	4516 So. Cooper St.	Arlington TX 76001
19. Michael J. D.	1010 Ohio Ave	Corpus Christi TX 78404
20. Robert L. D.	812 Friends Ln.	Friederichsburg TX 78629
21. Grea Bailey	2202 Durham	Brownwood TX 76801
22. Dr. D. D.	1712 D Street	Flora TX 78114
23. Michael D. D.	P.O. Box 1288	Mercer Is WA 98240
24. Dr. D. D.	555. Loop 380 off TX	Waco TX 76795
25. Dr. D. D.	12129 RR 620, Sta 330	Arantia Sp 78750



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Apothecary, Inc.

THE PROFESSIONAL COMPOUNDING PHARMACY
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TO: Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

We are compounding pharmacists who serve pet owners daily in our pharmacy compounding business. We fill prescriptions for pets of all kinds.

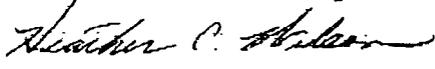
We are concerned about the CVM Compliance Policy Guide that could easily affect our ability to help our animal patients.

CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Examples include: methimazole for hyperthyroid cats and potassium bromide for seizures in dogs. We prepare metronidazole and doxycycline and amoxicillin as antibiotic treatment for most species. Our flavors and various dosage forms allow owners to medicate their pets. Pets are often very resistant to being treated and our compounding helps the owners to give the required medication and to keep their pets healthy.

This is our request for the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Heather C. Wilson, R.Ph., and Sheri Cannell, R.Ph. Pharmacists/Owners
Broadway Apothecary, Inc. 1712 Willamette St., Eugene, OR 97403
hwilson681@comcast.net

cc: Mark McClellan, FDA Commissioner
cc: Senator Ron Wyden
cc: Senator Gordon Smith
cc: Rep. Peter DeFazio
cc: IACP

November 19, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

The Center for Veterinary Medicine issued a Compliance Policy Guide that would prohibit compounding pharmacists from preparing medications from bulk source for non-food animals. This CPC guide was issued without a public comentary period.

This CPG was issued without a public comment period in violation of the FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

The CPG would severly limit my practice as a compounding pharmacist in the comtemporaneous preparation of medications for non-food veterinary patients. If I do not have these bulk chemicals available, there are numerous preparations that I will be unable to make from the existing tablets, capsules, or liquids. Even if I will be able to make a product from the existing products, they will be more expensive and less efficacious. The volume of fillers and excipients in tablets and capsules prohibit me from making most transermal products. An example this would be methimazole transdermal gel for feline patients. This product can not be made from the available tablets. A significant number of feline patients are difficult to dose at best and most are impossible to dose orally. These feline patients would have a defacto mandate preventing them from receiving the medication that they need for their hyperthroidism. It is imperative that I be able to prepare medications for these non-food animals where the appropriate dose, dosage form, or appropriate flavor is not available with the existing products. Liquid preparations are flavored for human patients and it is next to impossible to "change" the flavor (much less the concentration) of these products to suit the target animal. Most animals are extremely difficult to dose with liquid preparations for humans. Most clients (animal owners) will give up trying to dose their animal and will usually discontiue the medication to the detriment of the animal.

It is imperative that I have the bulk chemicals available to prepare capsules, oral liquids, transdermal creams and gels, and other medicinal products that are not comercially available. These animals will not have medication availble to them in a significant number of situations if I am limited according to the CPG.

I have a "wall of pictures" of animals from dogs, cats, birds, guinea pigs, tortoises, etc that the animal's owners have brought me in appreciation of the medications that I made from their animals that would otherwise be unavailable to them according to this CPG. With bulk chemicals available, I can prepare these products in the correct dose, the best dosage form, and appropriately flavored for the target animal. The compounding pharmacist is the best equipped and education professional to prepare these medications

Please reconsider opening the CPG to a public comment period for further consideration.

Sincerely,

Steven E. Bonham Pharm. D
Fair Oaks Pharmacy
1051 Grand Ave
Arroyo Grande, Ca 93420
805-489-4235

cc FDA Commissioner Mark McClellan
The Honorable Dianne Feinstein
The Honorable Barbara Boxer
The Honorable Lois Capps
IACP

THE WELLNESS PHARMACY

11/16/2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Sir:

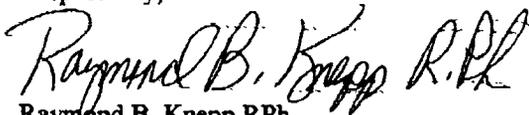
It has come to my attention that the Center for Veterinary Medicine issued a Compliance Policy Guide in final form without allowing opportunity for comments in violation of FDA Good Guidance Practices. Many of the requirements of this CPG are extremely problematic and deserve a period of comment before being put into effect.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Because some manufactured products such as diethylstilbestrol, phenylpropanolamine and cisapride are no longer available, compounding from bulk chemicals is the only way to provide relief for problems of urinary incontinence or gastrointestinal motility. Even when a manufactured product such as methimazole is available the excipients present in crushed tablets preclude creating a gel dosage form which is most convenient to pet owners and the method least stressful for pets to receive, especially cats. These are only a few examples of many instances by which compounding from bulk chemicals is necessary to provide optimal veterinary care.

Lastly, it is obvious to both professional and lay persons in this country that this CPG is solely to protect market share of the major pharmaceutical companies instead of looking to the common good and the needs of citizens in caring for their pets.

Respectfully,


Raymond B. Knepp RPh

cc: FDA Commissioner Mark McClellan, MD, Ph.D.
Senator John Warner
Senator George Allen
Representative Frank Wolf
IACP



PORTAGE PHARMACY

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FAX (269) 327-2709

November 15, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine (CVM)
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am writing today to express my deep concern about the CVM's recently issued Compliance Policy Guide (CPG). As you know, the CPG was issued in final form without allowing for comments which is in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition against compounding from bulk active pharmaceuticals creates problems across the board: Pets...many will die; Pet Owners... Many will suffer unnecessary grief; Veterinarians...their ability to practice veterinary medicine effectively will be severely limited; Pharmacists...their participation in to coordinated approach to health care of non-food producing animals will be severely and negatively affected.

Please withdraw the CPG in question and reissue it in draft form to allow for pet owners, veterinarians, and pharmacists to comment on its provisions before it is implemented.

Sincerely,

Lawrence D. Curtis, R.Ph.

Lawrence Curtis, R.Ph.

Vice President

Phone 269-327-0033/Fax 269-327-2709/email ips@net-link.net

cc: Mark McClellan, Ph.D., FDA Commissioner
U.S. Senator Carl Levin
U.S. Senator Debbie Stabenow
U.S. Representative Fred Upton
IACP

THE MEDICINE SHOPPE
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Kevin D. Goodson, R.Ph.
8351 N. Century Blvd., Century, FL 32535
Phone: (850) 256-3900 Fax: (850) 256-0075
Email: www.medicineshoppe.com

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

11/5/2003

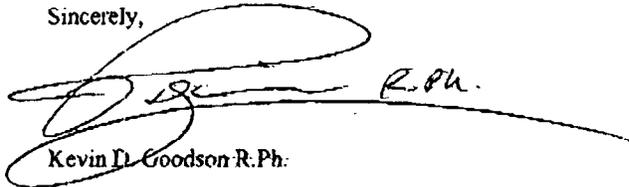
Dear Sir:

I am writing concerning the recent Compliance Policy Guide (CPG) on compounding drugs for animals that disallows all compounding from bulk pharmaceutical ingredients. I am concerned about the impact these restrictions will have on America's pet owners.

It is essential that pharmacists be allowed to compound from bulk drug substances for non-food producing animals. Bulk active pharmaceuticals are subject to the same strict standards as their manufactured counterparts as far as quality and purity, and it seems rather SEVERE to restrict something for animals that is NOT RESTRICTED to humans.

I understand the CPG was issued in final form without allowing opportunity for comments, which is in violation of FDA Good Guidance Practices. I ask you to please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on it's provisions before it is implemented.

Sincerely,



Kevin D. Goodson R.Ph.

KG/kdg

Cc: Mark McClellan, FDA Commissioner
Cc: Senator Bob Graham
Cc: Senator Bill Nelson
Cc: Representative Jeff Miller
Cc: IACP

The Pharmacy That's All About Your HealthSM



October 20, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I am writing you in response to the Compliance Policy Guide (CPG) on veterinary compounding that has been released in final form. Truthfully, along with others within this industry, I am surprised it was not released to the public for a comment period. Many requirements of this CPG are very problematic and deserve a comment period before being put into effect.

The most problematic prohibition in the CPG is against compounding from bulk active ingredients. Bulk active pharmaceuticals give you the purest form of an active chemical possible. This allows a compounding pharmacist to compound a drug with minimal compatibility issues. For example, we compound a prednisolone injection that has been off the market from manufacturers because of economic reasons. The only source of prednisolone would be from a finished tablet or syrup form. One cannot compound a high quality sterile injectable from crushed tablets. It is the inactive ingredients that pose the danger to using finished pharmaceuticals vs. bulk active (pure) ingredients. As an experienced Pharmacist, I know that due to inactive ingredients, there is no safe way to compound a sterile drug from a tablet or syrup due to the other inactive ingredients. From my professional view, this new CPG is asking for trouble from a safety standpoint.

I fully recognize the FDA's concern on compounded drugs being used in food producing animals. However, patient-specific compounding for companion animals is a vital service to the veterinary practice. UPI goes to great lengths to monitor what kinds of practices and animal our medications are dispensed to. This new CPG will all but destroy the highly needed service of compounding within the veterinary market. I ask you to reconsider the CPG, strike the prohibition on the bulk active ingredients, and reissue it with a comment period.

I thank you for your time and consideration for the improvement of healthcare. If you have any questions or comments, please call me at (888) 339-0874.

Sincerely,

A handwritten signature in black ink, appearing to read 'Travis Leeah', written in a cursive style.

Travis Leeah, R.Ph.
Compounding Pharmacist

cc. Congressman Chet Edwards

Custom Meds Pharmacy

Fast Professional Compounding

Wednesday, October 29, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

IACP

Copy

Dr Sundlof:

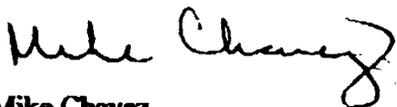
As the owner of a small compounding pharmacy, I was dismayed when I received notification of your recent Compliance Policy Guide disallowing all compounding from bulk pharmaceutical ingredients. This will effectively put me out of business.

Your agency issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG create foreseeable problems, not the least of which is holding animal compounding to a more restrictive standard than your policies governing human patients. Dramatic CPGs such as this one deserve a comment period before being put into effect.

Your prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. Pharmacists should be permitted to compound for non-food producing animals from bulk drug substances.

I hereby request that you withdraw the CPG and reissue it in draft form to allow all pharmacists, veterinarians, pet and animal owners input on this important subject prior to its implementation.

Sincerely,



Mike Chavez
President

cc: Senator Bob Graham, Senator Bill Nelson, Representative F. Allen Boyd, Mark McClellan, MD, PhD, FDA Commissioner

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Fax: (402)-486-4286

Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Sandish Place
Rockville, MD 20855

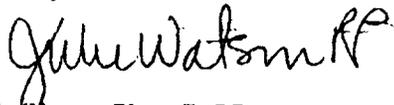
Dear Dr. Sundlof,

I am writing in regards into the Compliance Policy Guide issued by CVM in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before initiating.

We have several animal owners who previously were not able to administer a vital medication to their dog, cat, bird, etc., due to compliance issues because the cat would not take a pill or the dog would pick out a hidden tablet in cheese. As pharmacists, we are able to compound medications in the flavor, concentration or dosage form desired by the owner as prescribed by the veterinarian. We have numerous success stories of compounding a medication for an animal that otherwise would not improve its medical issue without compounding from a bulk pharmaceutical chemical. The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that the pharmacist be allowed to compound for non-food producing animals from bulk drug substances.

I am asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners to comment on its provisions before it is implemented.

Sincerely,



Julie Watson, PharmD, RP

cc: Mark McClellan, FDA Commissioner
cc: Senator Chuck Hagel
cc: Senator Ben Nelson
cc: Representative Doug Bereuter
cc: IACP



Allen Pharmacy, Inc.

Perry Kliewer, R.Ph.

580-772-3347

P.O. Box 389

Weatherford, Oklahoma 73096

November 4, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
US Food and Drug Administration (HFV-1)
301-443-3100

Dear Dr. Sundlof:

The recently issued Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients is a standard that is much more restrictive than FDA's policies governing compounding for human patients. The CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk active pharmaceuticals.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

George Perry Kliewer, R.Ph.

George Perry Kliewer, R.Ph.
580-772-3347/phone
580-772-3350/fax

Cc: Mark McClellan, FDA Commissioner
Senator James Inhofe
Representative Frank D. Lucas
International Academy of Compounding Pharmacists





ALVARADO MEDICAL PLAZA PHARMACY

5555 Reservoir Dr., Suite 114, San Diego, CA 92120
(619) 287-5035 • Fax (619) 287-5098

November 5, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. FOOD AND DRUG ADMINISTRATION
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

The CVM recently released a Compliance Policy Guide (CPG) regarding the compounding of veterinary medicines from bulk pharmaceuticals. As a compounding pharmacist, I'm concerned for the welfare of the animals I dispense to, their owners, and the veterinarians that I assist. All because of your department's CPG.

A prohibition of compounding for *non-food producing animals* would be a grave disservice for pets and their owners. Why, you ask? Because many commercially-available dosage forms are not suitable *all* the time for *all* domestic animals. That's why I make a lousy-tasting pill into an acceptable oral suspension. Or convert a bulk chemical into a transdermal gel for an animal that refuses anything by mouth (and bites the owner who dares to try an oral dose!).

Did you seek the opinion of any compounding pharmacy group when drafting the CPG? If not, why not? The International Academy of Compounding Pharmacists (IACP) would have given you a professional opinion of your CPG and its ramifications for compounding pharmacists like me.

It's ironic to me that the CPG would prohibit the dispensing of FDA-approved drugs for *non-food producing animals*. That just doesn't make any sense!

Dr. Sundlof, I'm requesting that you request a withdrawal of the CPG and reissue it in draft form so that the people most affected by it – pharmacists, veterinarians, and patients – can comment on its provisions *before* it is implemented.

Sincerely yours,

R.J. "Tad" Wolicki, R.Ph., C.D.E.
Compounding Pharmacist

Cc: Dr. Mark McClellan, FDA Commissioner

Cc: IACP



October 23, 2003

Dr. Stephen F. Sundlof
Director
Center for Veterinary Medicine
US Food and Drug Administration
7500 Standish Place
Rockville, MD 30855

Dear Dr. Sundlof:

The Center for Veterinary Medicine (CVM) recently issued a Compliance Policy Guide (CPG) prohibiting pharmaceutical compounding from bulk active pharmaceuticals. Since there is a shortage of veterinary labeled drugs and human dosage forms and strengths frequently cannot be used, and many effective pharmaceuticals have been discontinued by manufacturers, this prohibition will severely affect the ability to veterinarians to treat their patients. It is essential that pharmacists be allowed to continue to compound these products for non-food-producing animals.

Please withdraw this CPG and re-issue it in draft form to allow veterinarians, patient owners and pharmacists time to comment on its provisions before it is implemented.

Yours to good health,

Santo A. Garro, R.Ph.

SAG:rcs

CC: Mark McClellan, M.D., Ph.D. FDA Commissioner
Senator Hillary Clinton
Senator Charles Schumer
Congressman Sherwood Boehlert
Frank Mondt, D.V.M.
V. Chmielewicz, D.V.M.

Santo A. Garro, R.Ph, FACA
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Dr. Stephen Sundlof, Director
Center for Veterinary Medicine,
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am writing to express my concerns with CPG 7125.40 issued by the CVM.

1. CVM issued this CPG without allowing a comment period, in violation of FDA's own Good Guidance Practices. Aspects of the CPG are very problematic and should be allowed a comment period before being unilaterally decided on without input from the affected pharmacies and veterinarians and the owners of the animals being treated with these therapies.
2. In particular, I am very concerned with the provision that I will not be allowed to use bulk drug substances in compounding for animals. Why, that's even more onerous than human compounding regulations! Why? Are bulk drug substances unsafe for animals? I have many customers whose dogs will go into seizures when I can no longer use potassium bromide, as just one example. Cats will end up being euthanized when their owners can no longer control their hyperthyroidism with methimazole, for another.

Please withdraw this CPG and reissue it in draft form to allow for pharmacists, veterinarians and patients to comment on it before it is implemented.

Michael Walsh, R.Ph.
Compounding Pharmacist
Hilltop Pharmacy
1223 East Division
Mount Vernon, WA 98274
360-428-1710 voice
360-428-7847 fax

cc: Mark McClellan, FDA Commissioner
cc: Senator Patty Murray
cc: Senator Maria Cantwell
cc: Representative Rick Larsen
cc: IACP

Dr. Stephan Sundlof
Director, Center for Veterinary Medicine
U.S. Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am writing to express my concerns regarding the Compliance Policy Guide (CPG) about bulk compounding for veterinary medicines. The CVM wrote the guidance without the opportunity for a comment period. This is in violation of the FDA's Good Guidance Practices. There are many problems with this guidance that require a comment period.

The ability of pharmacists to compound medication for non-food animals from bulk active materials is essential. There are thousands of animals treated daily with medications that are no longer available, made possible by compounding pharmacists. Examples of these are Diethylstilbestrol (DES) for incontinence and Methimazole for thyroid treatment.

Compounding pharmacists work closely with veterinarians to help treat animals that have compliance problems or with medications no longer commercially available.

I am writing to ask you to withdraw the CPG and reissue it in draft form that would allow veterinarians, pharmacists and pet owners to comment on it's provisions before it is implemented.

Thank you for your attention to this matter.

Sincerely

Robert B. Lima, RPh.
Lima's Professional Pharmacy
2097 Harrison Ave.
Eureka, Ca. 95501
707-441-8500
707-441-9114 (fax).
rlima@cox.net

cc: FDA Commisioner Mark McClellan, Senators Diane Feinstein and BarbaraBoxer
Representative Mike Thompson, IACP

Paris Discount Pharmacy

3160 Clarksville St. * Paris, TX 75460
903-785-3414 * 903-785-1683

October 28, 2003

Senator John Cornyn (R-TX)
221 W. 6th St., Ste. 1240
Austin, TX 78701

Senator John Cornyn (R-TX),

The Center for Veterinary Medicine issued the Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I and the following Doctors of Veterinarian Medicine ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Thank you,



Gerry Teague RPh.
3160 Clarksville St.
Paris, TX 75460
(903) 785-3414

cc: Mark McClellan, FDA Commissioner; cc: Dr. Stephen Sundlof, CVM Director; cc: Senator Kay Bailey Hutchison (R-TX)/cc: Representative Max Sandlin, Jr. (D-TX 1st)

A petition has been adopted by the following doctors of veterinary medicine to express the views of how pharmaceutical compounding enhances their practice and the healthcare of their companion animal patients:



5200 EAST YALE CIRCLE
SUITE 200B
DENVER, CO 80222
(OFF) (303) 691-3377
(FAX) (303) 691-3378

EIN # 84 1229678

October 27, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

The role of government is to govern for the people and by the people. Unfortunately, the FDA has once again ignored this constitutional principle. The FDA has issued internal compliance policy guidelines (CPG) regarding compounding medications from bulk drugs for animals without public comment. This is unconscionable. That the FDA is trying to protect our food animal population is a parallel concern of mine. That the FDA has linked non-food animal drug compounding within its guideline is irresponsible and irrational.

The business of my pharmacy is human and non-food animal drug compounding from available bulk drugs. This CPG will adversely affect my livelihood and the eight people I employ. My pharmacy provides a necessary and regularly requested service to compound prescriptions for the non-food animal. The compounded prescriptions my pharmacy provides fills the void either vacated by the animal drug manufactures or ignored because of low economic return.

It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drugs. It is indefensible for the FDA not to open these internal compliance guidelines for public opinion. Many requirements of this Compliance Policy Guide are extremely problematic and deserve a public comment period prior to their effect. I urge the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions. I urge you to let the people be heard.

Sincerely,


Jerry Eubanks, RPh
President

cc: Senator Wayne Allard
Senator Ben Nighthorse Campbell
Congressman Tom Tancredo
Congressman Joel Hefley



October 20, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Re: Compliance Policy Guide on Veterinary Compounding.

Dear Dr. Sundlof:

The Compliance Policy Guide (CPG) on veterinary compounding was released in final form without allowing the opportunity for comments from the public and/or practitioners who must determine what is best for their patients and/or the patients' owners. The issuance of the CPG in final form prevented input and comments from the very professionals (veterinarians and pharmacists) and owners of veterinary patients most affected by the policy change. The CPG, as issued, denies veterinarians the ability to determine and insure safe, effective, timely, and adequate patient care.

Many requirements of this CPG are very problematic and deserve a comment period before being put into effect. The single most problematic prohibition in the CPG has to do with not allowing compounding with bulk active ingredients. Bulk active ingredients are the purest form of an active chemical possible. Using bulk active ingredients allows a compounding pharmacist to compound a drug with minimal contamination and compatibility issues. For example, many veterinaries prescribe a prednisolone injection. Without the pure active ingredient, the only forms of prednisolone available are in tablet or syrup form. We believe that it is very dangerous to the patient to incorporate non-pure drug products into a sterile injectable. There is simply no safe way to compound a sterile drug from a non-sterile tablet or syrup due to the other inactive ingredients. Using only pure, clean bulk drug substances—obtained from FDA-registered facilities—is a necessity in the compounding of high quality products. The prohibition must be removed for the pharmacist to serve the veterinary profession. The need to use bulk ingredients comes up repeatedly for veterinary drugs.

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76505-3094 • 254-933-0894
FAX 254-933-
0875

I am aware of the FDA's concern regarding compounded drugs being used on food-producing animals, and I agree with this concern. However, this can be prevented by proper labeling such as "**Prohibited for use on food-producing animals**".

Compounding for animals is a vital service to insure optimal patient care. The prohibition on the compounding of prescription drugs for animals from bulk active pharmaceutical ingredients will all but destroy this highly needed compounding service to veterinarians and their patients. I ask you to reconsider the Veterinary CPG and reissue it in draft form to allow pharmacists, veterinarians, and patient owners to comment on its provisions before it is implemented.

Thank you for your time and consideration. Please feel free to contact me at (888) 339-0874 for any questions or comments.

Sincerely,



Daniel (Dan) Volney
President

cc. Congressman Chet Edwards
Senators Hutchison and Cornyn

Central Pharmacy

2609 N. Duke Street, Suite 103
Durham, NC 27704
919-220-5121 FAX 919-220-6307

Bill Burch, RPh, FACA Jennifer Burch, Pharm. D. CDE Sloan Barber, Pharm. D.

October 26, 2003

Dr. Stephen Sundolf, Director
Center of Veterinary Medicing
U. S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundolf:

The FDA's prohibition in this CPG against compounding from bulk active e pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. If you have ever tried to give a cat medication by mouth you would understand the difficulty many cat owners experience. Seeing your dog have uncontrolled seizures is not a pleasant sight. Each of these examples requires compounding from bulk pharmaceuticals. These are just two simple examples of the situations that present daily to the veterinarian and compounding pharmacist. Without the ability to compound from bulk pharmaceuticals there is no solution for these owners.

CVM issued the Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. As previously stated many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. Please extend the courtesy of a comment period so you may hear why this policy needs to be revised.

Again as a courtesy the many pet owners in this country please withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and pet owners to comment on its provisions before being enforced.

Sincerely,



William Burch, RPh, FACA

Cc: Dr. Mark McCellan, Commissioner FDA
Sen. Elizabeth Dole
Sen. John Edwards
Rep. David Price

October 23, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

The Compliance Policy Guide issued by the Center for Veterinary Medicine regarding compounding of prescriptions for non-food producing animals is extremely problematic. It is essential that pharmacists be allowed to compound from bulk pharmaceuticals for a variety of ailments not satisfied by the mass produced medicines of the drug companies.

It would be very helpful for the Center of Veterinary Medicine to allow comment prior to issuing the guidelines in final form.

Our pharmacies have dozens of pet owners that are very fearful their pets will suffer because of the Center's action. Veterinarians and pet owners alike are very concerned and as such are circulating petitions to encourage the Center for Veterinary Medicine to modify these guidelines. These petitions will be forwarded to your department.

In closing, I ask that the Compliance Policy Guidelines be re-issued in draft form to allow pharmacists, veterinarians, and patients time to comment prior to implementation.

Thank you.

Sincerely,



T.J. Johnsrud
President

Cc: Mark McClellan, FDA Commissioner
Senator Chuck Grassley
Rep. Jim Leach
Rep. Jim Nussle

Rep. Tom Latham
Senator Tom Harkin
Rep. Leonard Boswell
Rep. Steve King

Corporate Office
1002 Sixth Street, Box 215
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FAX: 515-382-6802

5770 N. MoPac Expressway
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FAX: 512-454-9866

1150 Fifth Street, Ste. 140
City Center, Coralville, IA 52241
Phone: 319-354-6006
FAX: 319-354-6050

209 East San Marnan
Waterloo, IA 50702
Phone: 319-236-8891
FAX: 319-236-9665



October 21, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration(HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen F. Sundlof,

I am writing to convey my concerns with the Compliance Policy Guide(CPG) issued that threatens my ability to compound many products for my veterinary patients. CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I want to ask FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Howard Hudgens

W. Howard Hudgens, RPH.
Heritage Pharmacy
1507 Springhill Avenue
Mobile, AL 36604
(251)432-0718

cc: Mark McClellan, FDA Commissioner
cc: Representative Jo Bonner
cc: Senator Jeff Sessions
cc: Senator Richard Shelby
cc: International Academy of Compounding Pharmacists

October 21, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration(HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen F. Sundlof,

I am writing to convey my concerns with the Compliance Policy Guide(CPG) issued, that threatens my ability to compound many products for my veterinary patients. CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I want to ask FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely, *Mary DeLoach*

Mary DeLoach, Store Clerk
Heritage Pharmacy
1507 Springhill Avenue
Mobile, AL 36604
(251)432-0718

cc: Mark McClellan, FDA Commissioner
cc: Representative Jo Bonner
cc: Senator Jeff Sessions
cc: Senator Richard Shelby
cc: International Academy of Compounding Pharmacists

October 22, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration(HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen F. Sundlof,

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I want to ask FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,



Jacquelyn Bell, Customer
Heritage Pharmacy
1507 Springhill Avenue
Mobile, AL 36604
(251)432-0718

cc: Mark McClellan, FDA Commissioner
cc: Representative Jo Bonner
cc: Senator Jeff Sessions
cc: Senator Richard Shelby
cc: International Academy of Compounding Pharmacists

APOTHÉCURE

CUSTOM PHARMACEUTICAL/NUTRITIONAL SOURCING

October 21, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
Fax: 301-827-4401

Re: Compliance Policy Guide on Compounding for Animals

Dear Dr. Sundlof:

Please consider withdrawing this un-challenged policy and rewriting it with input from those involved, such as veterinarians, compounding pharmacists, and pet owners. Compounding for humans from bulk active pharmaceuticals has been an accepted practice for years, and to disallow this for non-food animals is very problematic and will warrant much investigation on underlying reasoning.

We are involved with many top notch veterinarians across the country, have a vet consultant on staff, and we are highly respected in our knowledge of vet medicine. This ruling certainly is very disconcerting for not only us, but our clients.

I am anxious to hear your feedback on this issue which, to this point, has had no public discussion.

Sincerely,



Joe Gallucci, RPh
Pharmacist-In-Charge, ApothéCure, Inc.
jgallucci@apothecure.com

cc: Mark McClelland, FDA Commissioner
US Senator Kay Bailey Hutchison (R-TX)
US Senator John Cornyn (R-TX)
US Representative Pete Sessions (R-TX 32nd)
State Senator Florence Shapiro (R-8)
State Representative Ken Marchant (R-115)
L.D. King, IACP Executive Director

APOTHÉCURE

CUSTOM PHARMACEUTICAL/NUTRITIONAL SOURCING.

October 21, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
Fax: 301-827-4401

Re: Compliance Policy Guide on Compounding for Animals

Dear Dr. Sundlof:

Please consider withdrawing this un-challenged policy and rewriting it with input from those involved, such as veterinarians, compounding pharmacists, and pet owners. Compounding for humans from bulk active pharmaceuticals has been an accepted practice for years, and to disallow this for non-food animals is very problematic and will warrant much investigation on underlying reasoning.

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I am anxious to hear your feedback on this issue which, to this point, has had no public discussion.

Sincerely,



Gary Osborn, RPh, CCN
President, ApothéCure, Inc.
garvo@apothecure.com

cc: Mark McClelland, FDA Commissioner
US Senator Kay Bailey Hutchison (R-TX)
US Senator John Cornyn (R-TX)
US Representative Pete Sessions (R-TX 32nd)
State Senator Florence Shapiro (R-8)
State Representative Ken Marchant (R-115)
L.D. King, IACP Executive Director