

Medicap Pharmacy
339 St. Patrick
Rapid City, SD 57701
October 8, 2003

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

Dear Sir,

I am extremely concerned about the recent issuance of the Compliance Policy Guide for Veterinary Compounding. I understand that this document disallows all compounding from bulk pharmaceutical ingredients. This is much more restrictive than the FDA's policy regarding compounding for human patients. Surely you cannot mean that pet owners nationwide will no longer be able to get the drugs they need for their small animals. After all, these are non-food producing animals.

For example, we compound benzodiazepine doses in fruit-flavored syrup for birds who would otherwise pick all their feathers off. We compound potassium bromide from bulk in beef-flavored liquid form for dogs who would otherwise suffer seizures.

Please withdraw this extremely restrictive Vet CPG and reissue it in draft form. Obviously, this CPG was issued without input or comments from those in the practice of veterinary medicine. This is in flagrant violation of the FDA Good Guidance Practices, so please reconsider your actions.

Jo Prang, RPh
VP of Operations



cc: Mark McClellan, FDA Commissioner
cc: Senator Tom Daschle, Senator Tim Johnson
and Rep. Bill Janklow.
cc: IACP and PCCA



Triangle Compounding Pharmacy

311-DD Ashville Avenue
Cary, NC 27511

Phone: 919-858-0809
Fax: 919-858-5145
Email: homeiv@mindspring.com

October 8, 2003

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

Dear Dr. Sundlof;

This letter is in regards to the recently issued Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients.

My pharmacy is a community based, local provider of compounded medications for both humans and companion animals. We do not provide medications for food producing animals. I have a number of concerns with this CPG:

- CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices.
- FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is **very problematic**. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Many of the animals we care for are only able to receive their medication because we have access to bulk active pharmaceuticals, thus allowing us to prepare dosage forms and flavors that the animals will accept. If we cannot prepare appropriate dosage forms for birds, cats and dogs, these animals may have to go without their medicine.

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

Sincerely,

Joe Cabaleiro R.Ph.

cc: Sen. John Edwards, Sen. Elizabeth Dole, Rep. David Price, Mark McClellan, MD, Ph.D.

The Medicine Shoppe Pharmacy
David Hilton, Owner/Pharmacist
625 West Elk Avenue
Elizabethton, TN 37643

Telephone (423) 547-0696
Fax (423) 547-9147

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 writing to inform you that the recent issuance of the Compliance Policy Guide on Compounding for animals, that disallows all compounding from bulk pharmaceutical ingredients is without merit and unfair to Pharmacist's rights. First of all, 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. Secondly, 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. And finally, this appears to be the latest in an ongoing mission by the FDA to deprive the right of Pharmacists to compound and patient's the right to choose compounding, a very disturbing thought.

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 Hilton, D.Ph.
Medicine Shoppe Pharmacy
625 West Elk Avenue
Elizabethton, TN 37643
423.547.0696
fax: 423.547.9147
medshoppp@preferred.com

cc: Mark McClellan, FDA commissioner
Rep. William Jenkins (R-TN 1st)
Senator Lamar Alexander (R-TN)
Senator Bill Frist (R-TN)
IACP

September 10, 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 recent Compliance Policy Guide(CPG) issued that threatens our ability to compound many products for 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, as well as veterinarians to write prescriptions that require the use of bulk drug substances. Working as a veterinary technician I have witnessed very success outcomes with our doctor's having the choice to write prescriptions requiring the use of drugs that come from bulk drug substances. If this Compliance Policy Guide is passed it would prove to be unjust to not only our veterinarians and pharmacists but most of all our patients.

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,



Eric T. Remines
Veterinary Technician
1575 Knollwood Drive
Mobile, AL 36609-2555
(251)753-9878

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

September 10, 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 our 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, as well as veterinarians to write prescriptions that require the use of the bulk drug substances in question. Many of our non-food producing patients have been successful with the use of their compounded medications which come from bulk drug substances. If this Compliance Policy Guide is passed it would prove to be unjust to our patients.

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,



Tammy R. Cregger
Compounding Pharmacy Technician
Heritage Pharmacy
1507 Springhill Avenue
Mobile, AL 36604
(251)432-0718

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

**BLOOMING GROVE PHARMACY
1200 ROUTE 208, SUITE #1
MONROE, NEW YORK 10950
(845) 782-2260**

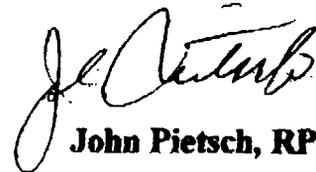
IACP

To Whom It May Concern:

We are concerned about the Compliance Policy Guide concerning compounding for animals from bulk pharmaceutical ingredients. The CPG was issued in final form without any opportunity for comments.

It is important for pharmacists to be allowed to compound for non-food producing animals from bulk drug substances. Compounding is a normal function of pharmacy practice. It is very helpful for patients when the dose or dosage form is not commercially available. The cost to the patients' owners is much lower; the quality of the finished compound is more elegant due to less excipient ingredients and easier for the owners to administer to their pets.

We are requesting that the F.D.A. withdraw the CPG and reissue it draft form to allow for comments before implementation.



John Pietsch, RPh.

**cc: Mark McClellan, FDA Commissioner
cc: Senator Hillary Clinton
cc: Senator Charles Schumer
cc: Representative Sue Kelly
cc: IACP**



Submitted Via Fax
(301) 827-4401
October 10, 2003

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:

As a compounding pharmacist I routinely compound medications for several ill dogs and cats. I have several concerns with the Compliance Policy Guide as listed below.

- 1) The Center for Veterinary Medicine issued the Guide in final form without allowing opportunity 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.
- 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.

Please 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,

Terry Purcell, R.Ph.
Pharmacy Manager
Both Worlds Pharmacy
2183 West Green Oaks Blvd.
Arlington, Texas 76013
(817) 451-5003
(817) 451-5393 Fax
tpurcell@bothworldsrx.com

cc: Mark McClellan, FDA Commissioner
cc: Kay Bailey Hutchison, Senator
cc: John Cornyn, Senator
cc: Joe Barton, Representative
cc: International Academy of Compounding Pharmacists



Submitted Via Fax
(301) 827-4401
October 10, 2003

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:

As a compounding pharmacist I routinely compound medications for several ill dogs and cats. I have several concerns with the Compliance Policy Guide as listed below:

- 1) The Center for Veterinary Medicine issued the Guide in final form without allowing opportunity 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.
- 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.

Please 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,

A handwritten signature in black ink that reads "Stephanie Erwin".

Stephanie Erwin
Doctor of Pharmacy
Both Worlds Pharmacy – Pharmacist in Charge
2183 West Green Oaks Blvd
Arlington, Texas 76013
(817) 451-5003
(817) 451-5393 Fax
serwin@bothworldsrx.com

cc: Mark McClellan, FDA Commissioner
cc: Kay Bailey Hutchison, Senator
cc: John Cornyn, Senator
cc: Joe Barton, Representative
cc: International Academy of Compounding Pharmacists



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.

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

October 10, 2003

Re: Veterinary Compounding CPG

Dr. Sundloff,

I am responding to the FDA's Center for Veterinary Medicine's recent decision to issue a Compliance Policy Guide (CPG) on compounding for animals that disallows compounding from bulk pharmaceutical ingredients. The veterinary pharmaceutical industry is very underserved and this restriction would further diminish the ability of Veterinarians to customize their patient's care. In addition, this guidance was issued in final form without allowing a comment period, in violation of FDA's Good Guidance Practices.

Veterinarians often call on compounding pharmacist to customize medications with special strengths, dosage forms, concentrations and even flavors, which are not available commercially. While these cases are the exception, they are vital to veterinary patient care. If pharmacists are not allowed to use bulk chemicals for compounding for animals, veterinarians will be unable to treat patients that require specialized or discontinued medications.

The decision to issue the Compliance Policy Guide that disallows compounding from bulk pharmaceutical ingredients is misguided and should be withdrawn and reissued in draft form to allow pharmacist, veterinarians, and their clients to comment on its provisions before it is implemented.

Respectfully yours,

Eric Vidrine, PD, FIACP, FACA

cc Mark McClellan, FDA Commissioner; Senator John Breaux; Senator Mary Landreiu;
Congressman Chris John, IACP

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

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October 10, 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,

Kathy Hurst RPh.
Kathy Hurst, 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

Dr. Stephen Sundlof, Director (FAX 301-827-4401)
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 this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments and I believe that this is in violation of FDA Good Guidance Practices. Many requirements of this CPG are complicated and really 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.

Often, veterinarians use human medications to treat pet problems. When the human dose is not suited for an animal or when the human version is removed from the market (sometimes for health reasons and sometimes for economic reasons), the pharmacist is called upon to make a treatment from bulk materials. This CPG threatens to deny veterinarians their right and duty to prescribe the treatment they deem best for their patients.

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,



Patricia A. Frieders, R.Ph.
The Compounder
575 W. Illinois Ave.
Aurora, IL 60506
630-859-0333 FAX 630-859-0114
Larry@theCompounder.com

cc: Mark McClellan, FDA Commissioner (FAX 301-443-3100)
Senator Dick Durbin (FAX 202-353-0150)
Senator Peter Fitzgerald (FAX 202-228-1372)
Representative J. Dennis Hastert (FAX 630-406-1808)
IACP (FAX 281-495-0602)

Dr. Stephen Sundlof, Director (FAX 301-827-4401)
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 this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments and I believe that this is in violation of FDA Good Guidance Practices. Many requirements of this CPG are complicated and really deserve a comment period before being put into effect.

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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,



Joel R. Frieders, Technician
The Compounder
575 W. Illinois Ave.
Aurora, IL 60506
630-859-0333 FAX 630-859-0114
Larry@theCompounder.com

cc: Mark McClellan, FDA Commissioner (FAX 301-443-3100)
Senator Dick Durbin (FAX 202-353-0150)
Senator Peter Fitzgerald (FAX 202-228-1372)
Representative J. Dennis Hastert (FAX 630-406-1808)
IACP (FAX 281-495-0602)

Dr. Stephen Sundlof, Director (FAX 301-827-4401)
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 this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments and I believe that this is in violation of FDA Good Guidance Practices. Many requirements of this CPG are complicated and really 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 dogs, for example, have seizure problems that have traditionally been treated with phenobarbital. There is a strong body of evidence that long term use of that drug does serious damage to the liver. Using potassium bromide also relieves seizures but does not damage the liver. Untold numbers of pets would be denied this helpful treatment if this CPG is enforced.

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,



Lydia J. Lesniak, Technician
The Compounder
575 W. Illinois Ave.
Aurora, IL 60506
630-859-0333 FAX 630-859-0114
Larry@theCompounder.com

cc: Mark McClellan, FDA Commissioner (FAX 301-443-3100)
Senator Dick Durbin (FAX 202-353-0150)
Senator Peter Fitzgerald (FAX 202-228-1372)
Representative J. Dennis Hastert (FAX 630-406-1808)
IACP (FAX 281-495-0602)

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,



Terry T. Parker, Pharmacy Technician
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.

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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,



**Jean Lott, 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**

Dr. Stephen Sundlof, Director (FAX 301-827-4401)
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundloff;

The Center for Veterinary Medicine issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments and I believe that this is in violation of FDA Good Guidance Practices. Many requirements of this CPG are complicated and really 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 dogs, for example, have seizure problems that have traditionally been treated with phenobarbital. There is a strong body of evidence that long term use of that drug does serious damage to the liver. Using potassium bromide also relieves seizures but does not damage the liver. Untold numbers of pets would be denied this helpful treatment if this CPG is enforced.

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,

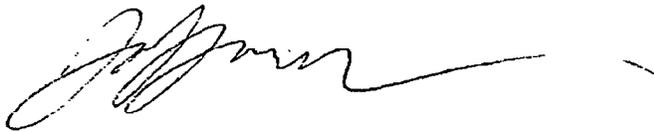

Lawrence J. Frieders, R.Ph.
The Compounder
575 W. Illinois Ave.
Aurora, IL 60506
630-859-0333 FAX 630-859-0114
Larry@theCompounder.com

cc: Mark McClellan, FDA Commissioner (FAX 301-443-3100)
Senator Dick Durbin (FAX 202-353-0150)
Senator Peter Fitzgerald (FAX 202-228-1372)
Representative J. Dennis Hastert (FAX 630-406-1808)
IACP (FAX 281-495-0602)

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

I am a third generation pharmacist and I love compounding. My veterinary patients are very dear to me and require my services in order to continue with a good quality of life. When I heard what was happening I was shocked. Why would the government restrict pharmacists from helping patients? When I was back in pharmacy school, I took an oath. Part of that oath was to provide the best care possible to my patients. In order for me to compound the best possible prescriptions for my patients, I need to have access and the ability to use bulk pharmaceutical grade chemicals. Restricting me from using these would not only decrease the quality of some compounds, it would make other compounds impossible to make. There are numerous compounds that we make for animals where a commercial product is not available in any form. If you could show me that we, as compounding pharmacists, are causing more harm than good by compounding with bulk chemicals, I will listen and do what is best for my patients. Otherwise, this new ruling would be a tragic mistake costing many animals the quality of life they have now.

I am truly disgusted that 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. In order to serve the public's best interest, and for the benefit for the health and wellness of the animals in question, the FDA should 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.



Jeff Carson R.Ph.
Oakdell Pharmacy
7220 Louis Pasteur
San Antonio, TX 78229
210-614-6200

cc: Mark McClellan, FDA Commissioner
cc: IACP

Island Pharmacy Services, Inc.

www.islandpharmacy.com

P.O. Box 1412
Woodruff, WI 54568
Tel. (715) 358-7712 Fax (715) 358-7021

Toll Free 800-328-7060

October 7, 2003

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

Dr. Sundlof:

The recent issuance of the FDA Compliance Policy Guideline restricting the use of bulk chemicals for compounding for animals is a major step backwards. Our concern is strictly related to the use of bulk chemicals for non-food producing animals, that is, pets.

As you are aware, this prohibition is a step backwards in time to the antiquated standards of the FDA prior to the FDA Modernization Act of 1997. Prior to this law, we were faced with the same prohibitions - which were nonsensical and unenforceable then, and are still today.

We have no problem with the FDA wanting to control the introduction of unapproved drugs into the food chain. However, the reality is that bulk chemicals are vitally necessary in the practice of pharmacy. Compounded prescriptions for an individual patient are often prescribed due to unavailability of a suitable manufactured dose. Sometimes the commercial dose has been discontinued for economic (NOT safety) reasons by the manufacturer. The ONLY option is the compounding of the prescription from bulk chemicals.

This reality is recognized and allowed (albeit reluctantly) by the FDA for human patients. We are in complete compliance with ALL regulations when we receive a prescription from a MD, and then compound a prescription for a human patient. However, under the current CPG, we are not in compliance when we receive a prescription from a veterinarian and compound a prescription for a pet using the same chemical. For example, we can compound a suspension of metronidazole (from bulk powder) for a child but cannot for a dog.

Does this make any sense? We have over 15,000 veterinarians and 50,000 pet owners who would argue that these medications are necessary. All have used our services for medications unavailable if not compounded from bulk chemicals. Should I ask them to contact you? Is this just another regulation that is on the books, but no one plans to ever enforce, just to use as a threat at some point in the future? Is this another backdoor attempt to limit the legitimate practice of prescription compounding?

It is evident (from the previous passage of the FDAMA 1997) that the legislature wants the FDA to NOT infringe on our ability to practice pharmacy - including the compounding of medications on a prescription basis. I urge you to remove the provision in the CPG related to the use of bulk chemicals for nonfood producing animals. The removal of this inconsistency will prevent the loss of high-paying jobs and have absolutely NO effect on the safety of the food chain.

Sincerely,



Randy Reek
President

CC. Senator Herb Kohl, Senator Russ Feingold, Representative Mark Green

Mark McClellan, FDA



A B R A M S
R O Y A L
P H A R M A C Y

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

October 2, 2003

Dr. Sundlof,

I am writing to express my concern for the recently issued Compliance Policy Guide (CPG) by the FDA Center for Veterinary Medicine (CVM). As it stands, this guideline will prove to be very detrimental to the health and welfare of many pets and animals.

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

The FDA's prohibition in this CPG against compounding veterinary medications from bulk active pharmaceuticals is extremely problematic in that many quality compounds can come only from using bulk pharmaceuticals.

In our practice, the compounding of pharmaceuticals to meet the specific needs of individual patients is crucial. Without these medications, the quality of life for many family pets will falter. Some of the conditions for which we provide compounded medications include: seizure control, inappropriate spraying/wetting, hypertension, hyperthyroidism and diabetes. Without the ability to compound with pure bulk chemicals, the very lives of several pets and animals will be at stake.

As you know, a family pet is more than a mere animal. A pet is a part of the family and deserves the same respect and care as any other family member. For some people, their pets are the only family they have left, and it is up to the medical community to make sure that measures are in place to ensure proper medical care without hindrances from faulty legislatures.

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

Sincerely,

Don Bottoni, RPh.

Don Bottoni, RPh.

cc: FDA Commissioner Mark McClellan, MD, PhD
Senator Kay Bailey Hutchison
Senator John Cornyn
Representative Pete Sessions
International Academy of Compounding Pharmacists (IACP)

8220 Abrams Road
Dallas, Texas 75231
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Toll Free: 800-458-0804
Fax: 214-341-7966



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Specializing In Your Health

October 10, 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 a compounding pharmacist in Grand Rapids, MI. My practice specializes, among other areas, in the treatment of animals and animal diseases. Many of these animal patients and their owners will be unable to continue to receive their medications if the Center for Veterinary Medicine (CVM) Compliance Policy Guide (CPG) is allowed to become law. The FDA has long recognized custom compounding for human patients on the order of a physician's prescription as part of the customary practice of pharmacy. Why has the FDA taken a more restrictive stance on veterinary compounding than on human compounding?

This policy is troubling because first of all because 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.

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. Compounding from FDA approved commercial products often presents a difficulty because the excipients used in the commercial product are unacceptable in taste or texture to the animal or provide so much bulk to the compound that it cannot be successfully made.

If this CPG is implemented, what can we do for a pet rat that had her nose accidentally broken when her owner shut it in the door? Try to force it to take over the counter ibuprofen or start with a custom compound that the pet will take without further trauma.

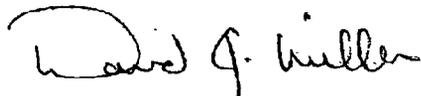
How about the cat whom the owner cannot give a pill? Should this animal be forced to spend weeks in an animal hospital so that a technician can give the cat its daily meds, or should my pharmacy be allowed to compound a pleasant tasting compound for the cat (triple fish based, for example) that the owner can easily administer? In many instances, we can make a transdermal gel which allows an even less traumatic means

of administering medications to animals.

We have literally hundreds of examples in my practice alone where compounded medications using bulk substances have not only improve the quality of the animals' lives, but in some instance, have saved the animals from death.

I am asking 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.

Thank you for your consideration,



David J. Miller, R.Ph., Ph.D.
Pharmacy Manager and Chief Formulation Scientist

djm/DJM

CC: Hon. Tommy G. Thompson, Secretary Department of Health and Human Services
Mark McClellan, MD, Ph.D., FDA commissioner
Senator Carl Levin, Michigan
Senator Debbie Stabenow, Michigan
Rep. Vernon Ehlers, Michigan's 3rd District



**Compounding
Lab**
at The Medicine Shoppe®
Alan M. Weissman, Pharm. D.
Compounding Pharmacist
64 Four Seasons Center, Chesterfield, MO 63017
Olive & Woods Mill

October 1, 2003

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

Dear Dr. Sundlof:

I am writing re: the new Compliance Policy Guide (CPG) just released in final form from the FDA in violation of FDA's Good Guidance Practices. The new CPG did not allow for comments from affected individuals (pharmacists, veterinarians and pet owners).

The CPG is especially problematic for the non-food producing animals that are the entirety of my veterinary pharmacy practice. It is essential that I be able to compound from bulk compounds. This restriction would make the provision of many therapeutic compounds unavailable to patients.

For example, for cats I have prepared Diltiazem in a Transdermal gel that is placed in the non-hairy area of the cats ear for treatment of cats with Supraventricular Tachyarrhythmias, Hypertrophic Cardiomyopathy, and /or Hypertension. This gel could NOT effectively be made from "ground up" Diltiazem tablets due to the fillers, binders and dyes in the commercial tablet. This compound is easily made from bulk drug powder.

Similarly, Methimazole Transdermal gel for cats is another compound that could NOT effectively be made from "ground up" Methimazole tablets due to fillers, binders and dyes in the commercial tablet.

There are many other similar examples of compounds that would not be able to be compounded without the use of bulk powders.

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

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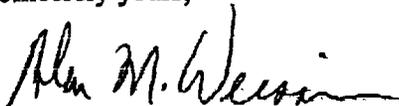
Dr. Stephen Sundlof

Page 2

October 1, 2003

If you have any questions regarding the impact of this CPG on my veterinarian patients please do not hesitate to contact me.

Sincerely yours,



Alan M. Weissman, Pharm.D.

Compounding Pharmacist

Fax: (314) 579-9200

Email: stlcompounder@aol.com

cc: Mark McClellan, FDA Commissioner

cc: Todd Akin, Representative

cc: Jim Talent, Senator

cc: IACP

- g. Commercially unavailable injections, no longer available through U.S. manufacturers
- h. Commercially unavailable eye and ear preps, i.e. cephalosporins, amphotericin, miconazole, clotrimazole, ketoconazole, vancomycin, ceftazidime.

I have asked our local vets to send letters to you also. We are also informing the responsible parties for our animal patients suggesting they contact you. I understand that this particular CPG was issued without the required hearings. I ask that you retract the current CPG and re-introduce it in draft form with the appropriate hearings occurring. Compounding for animals is a fantastic patient service. It would be a shame to make it not available.



Barry Smith, Pharm D
Compounding Pharmacist

Cc: FDA Commissioner Mark McClellan, MD, Ph.D.
Senator Diana Feinstein
Senator Barbara Boxer
IACP

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

Shawn Needham
903 S. Ironwood Dr.
Moses Lake WA 98837
(509)764-2314
mlrx@genext.net

Dear Dr. Sundlof:

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 FDA's policies governing compounding for human patients. Many requirements of the CPG are problematic and deserve a comment period before being put into effect.

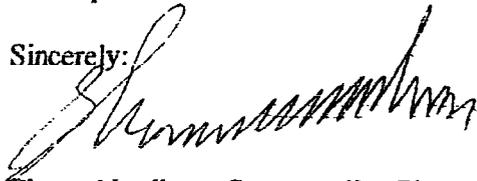
The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

For example, I compound prescriptions of potassium bromide for dogs to prevent seizures. Veterinarians use this as a second line agent in combination with other agents after the commercially available alternatives have been tried. There is no commercially available potassium bromide. I would hate to see owners have to watch their dog be in a seizure (some up to 1 hour at a time), and possibly get brain damage or have to be put to sleep, because of this new guideline.

Compounding is essential for veterinary medicine since the size of animals range from a 1 pound bird with pneumonia to a 1500 pound horse with Cushings disease. Without bulk drug substances, I could not help these animals. The commercial drug manufacturers cannot always help these animals because of the small numbers of them so it is not economically viable for them.

Compounding for animals, is a long time pharmacy tradition, please do not take away the ability of pharmacists to help animals. Please withdraw the CPG and reissue in draft form to allow veterinarians, patients and pharmacists the chance to comment, before it is implemented.

Sincerely:



Shawn Needham, Compounding Pharmacist



42 Timber Lane, South Burlington, VT 05403
Phone: 802-864-0812 Toll Free: 800-928-1488 Fax: 802-860-1489
Email mail@customrxshop.com Web: www.customrxshop.com

09/30/03

Dear IACP,

Here is a copy of the letter that I sent to Dr. Sundloff, Commissioner McClellan, our Vermont Representative Bernard Sanders and our Senators James Jeffords and Patrick Leahy.

I am a compounding pharmacist and prepare a few veterinary compounded prescriptions every day, including some that are life sustaining, for our clients' non-food use pets. I am writing to ask for your help in changing FDA's recent Compliance Policy Guide that prohibits the use of bulk compounding powders in prescriptions.

We prepare customized prescriptions for individual animals prescribed by their veterinarian. I work very closely with the local veterinarians and know many of them on a personal basis. We do not manufacture large amounts of product to sell at wholesale or to clients that we don't have a relationship with. We use bulk drug compounding powders that are of pharmaceutical quality equal to or higher than that required for human use. That is, they are tested and provided to me with certificates of analysis demonstrating that they meet USP (United States Pharmacopeial) standards. Occasionally we use NF powders, meeting National Formulary standards, which is only a difference of semantics and are of equally high quality. Rarely, there are veterinary drugs that do not have a USP/NF monograph. In that case we use drugs meeting the American Chemical Society (ACS) standards or other standards such as the British Pharmacopoeia. Very rarely there is no standard available, but again, we only buy drugs from compounding wholesalers who can provide us with a valid certificate of analysis demonstrating purity.

FDA's recent compounding Compliance Policy Guide (CPG) restricts us from using bulk powders for compounding. Instead we would be forced to use only veterinary or human approved tablets, capsules, elixirs, etc... to compound. The problem with this is that these approved products contain inactive ingredients that make compounding difficult or impossible.

For example, I make chewy cat treats for 1 cat that contain atenolol 6.25mg. The cat is very finicky and the treat is about 1/4 the size of a dime. I use atenolol, USP powder and can disguise it in the treat. However, if I were forced to use atenolol tablets it would be difficult to incorporate the tablet into the treat. This atenolol powder meets the same USP standards that are required for the drug in the tablet, but the CPG would force me to use the tablet and not the powder. This medication is necessary for this cat with a cardiac condition to live and if I had to use the tablets I would not be able to disguise the drug in the treat. This is just one example of how difficult the CPG would make it to serve veterinary patients.

CVM issued this Compliance Policy Guide 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 am requesting your assistance in withdrawing the FDA's CPG and reissuing it in draft form to allow for pharmacists, veterinarians, and patients to comment on it's provisions before it is implemented. If you have any questions, feel free to contact me.

Very Sincerely, Eric Brewer

Cc: Mark McClellan, FDA Commissioner; Senator Patrick Leahy; Senator James Jeffords; Representative Bernard Sanders; IACP

1 OCTOBER 2003

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 to you in concern over the recently issued Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients. The prohibition in this CPG is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals. We have so many animals that we treat here in the pharmacy that would suffer and even die because of such a regulation. At the very least quality of life for these animals would be greatly affected. Some animals just will not take medicine in current dosage forms and we enable the dose to be given as directed by the veterinarian by utilizing a different form. Cats are notorious for being able to hide a tablet and get rid of it up to a hour later. Some animals need a dose that is different from available doses based on size or age. By not allowing licensed veterinarians, experts in what the animals need, to write for the most effective drug and dosage form for the medicine to be delivered, this guideline is tying helpful hands. We believe the Center for Veterinary Medicine issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices and that many of these requirements are extremely problematic and deserve a comment period before being put into effect. We ask the FDA to withdraw the CPG and reissue it in draft form to allow for veterinarians, patients and pharmacists to comment on its provisions before it is implemented.

Sincerely,



John Urrutia, RPh.
Pharmacy Manager
Union Square Pharmacy
8015 W. Alameda
Lakewood, CO 80226
(303)274-7877 Fax (303)274-7974
J_URRUTIS@MSN.COM

**3 Rivers Compounding Pharmacy
602C South Morgan
Granbury, Texas 76048
(817) 573-2512
FAX (817) 573-3098**

10/2/03

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

Dear Dr. Sundlhoff,

I am writing to voice my concerns regarding the recent CPG issued in final form without any opportunity for comment. Some of the issues in this CPG are distressing to me and I feel that they deserve a comment period prior to becoming effective. I appreciate the FDA's stance on enforcement of appropriate policies for the overall good of the population; however there is also a population that will be underserved should the compounding of pharmaceuticals from bulk chemicals be prohibited in its entirety. Compounding for companion animals comprises a portion of our patient base. This population will no longer be able to access the medications we specially tailor. This includes transdermal methimazole gel for numerous cats. Owners are able to treat their cats for hyperthyroidism without having to "stuff" pills down cats throats (see cute attachment). We have also formulated things such as:

- Fluoxetine (prozac) for obsessive compulsive birds who pluck their own feathers
- Specialty items for our local wildlife reserve park, this has included concentrated antibiotic injectables for darting a giraffe
- PZI insulin which is no longer on the market for cats
- Multiple other transdermal products for treating cats

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

Sincerely,

Gamze Strain, RPh.

Gamze Strain, R.Ph.

Cc: Mark McCellan, FDA Commissioner
Senator Kay Bailey Hutchison
Senator John Cornyn
Representative Charles Stenholm
IACP

Fax: (301) 443-3100
Fax: (202) 224-0776
Fax: (202) 228-2856
Fax: (202) 225-2234
Fax: (281) 495-0602



10/13/2003

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 to express my sincere concern with the recently issued FDA VET CPG that severely restricts pharmacy prescription compounding for household pets and other animals that are not intended for human food production.

It appears that the CVM issued this Compliance Policy Guide in final form without allowing opportunity 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 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.

Our vet prescription compounding service meets many important needs of the pets of our customers. For example, we supply ursodiol for cats and dogs suffering from digestive problems related to gall bladder function. We supply potassium bromide in various dosage forms for seizure control in dogs. We supply methimazole in various dosage forms for cat's thyroid disorders. These are household pets, and these drugs won't get into human food supply. If we are prohibited to compound vet prescriptions, veterinarians will lose a very valuable resource in their day to day treatment of household pets and their medical problems.

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

Sincerely,

Barry W. Feely, RPh
Medicine Man Prairie Pharmacy
8093 N Cornerstone Dr.
Hayden, ID 83835
208 762 9355
medmanpharmacy@msn.com

cc: Mark McClellan, FDA Commissioner
cc: Sen. Mike Crapo, Sen. Larry Craig, Rep. Butch Otter
cc: IACP

Peoples Custom Rx

785 Brookhaven Circle East
Memphis, TN 38118
901-682-2273 Fax 901-682-4146

September 29, 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 a small businessman and pharmacist who compounds medications for animals as well as adults. The recently issued Compliance Policy Guide on compounding for animals would greatly affect the manner in which I practice pharmacy. My veterinary practice involves only non-food animals and would present a hardship for veterinarians, clients, and the patients.

The Compliance Policy Guide was issued in final form without the opportunity for comments. Not only is this a violation for FDA Good Guidance Practices, many of the requirements are 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 substances because of the practical aspects. Bulk pharmaceutical ingredients allow for more flexible dosing and therefore, more compliant clients (patients). To alter a commercial product is expensive and usually not as successful as using active ingredients.

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

Sincerely,

William C. Johns, D.Ph, F.I.A.C.P., F.A.C.A.
Owner Peoples Custom Rx

Los Altos Pharmacy
255 Second St.
Los Altos, CA 94022
650-948-1212 or fax 650-949-2269
pharmacist@losaltospharmacy.com

Dr. Stephen Sundlof
Center for Veterinary Medicine
U.S. Food & Drug Administration
7500 Standish Place
Rockville, MD 20855

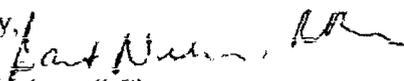
Dear Dr. Sundlof,

I am writing to voice my concerns regarding the Compliance Policy Guide concerning veterinary compounding issued by the CVM in final form before allowing opportunity for comments. This action was taken in violation of FDA Good Guidance Practices, which allow for input from various entities affected by such regulations. Many of the requirements of this CPG are very problematic for my compounding practice and certainly deserve a comment period before being put into effect.

Making a blanket rule against compounding from bulk active pharmaceuticals for non-food producing animals is not in the least in the public interest. Many of my clients are pet owners who require topical delivery medication to treat overactive thyroid conditions in their cats. One of the preparations I make is Potassium Bromide for uncontrolled seizures in dogs. The list goes on and on of products that are not currently available in the appropriate dosage forms or strengths for my veterinary customers.

I am requesting that you ask the FDA to withdraw the CPG and reissue it in draft form to allow for comments from pharmacists, veterinarians, and patient/pet-owners to comment on the provisions before it is implemented.

Thank you for your attention to this matter.

Sincerely,

Bart D. Nelson, R.Ph
Pharmacy Owner

Cc: Mark McClellan, FDA Commissioner
Senator Dianne Feinstein
Senator Barbara Boxer
Representative Anna Eschoo

HUNTSVILLE

COMPOUNDING
PHARMACY

2121-E WHITESBURG DRIVE • HUNTSVILLE AL 35801
256 425-0123 • FAX 256 425-0195

Jim Gillespie, R. Ph.
COMPOUNDING PHARMACIST

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

I have great concern about the FDA's prohibition of compounding from bulk active pharmaceuticals. In our compounding practice we assist many non-food producing animals with their health problems. This morning a parrot with itching feet received a compounded antihistamine. This relieves the itching so that the bird does not peck away at it's feet. We make methimazole transdermal gel for several cats with thyroid disorder. The commercially available tablets do not work well because of the fillers and other inert ingredients. In short compounding from bulk pharmaceuticals for non-food animals offers many benefits for the animals and no risk for the food we eat.

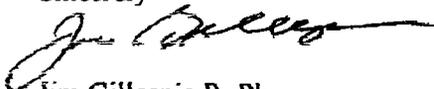
I object to the following:

(A) CVM issued this Compliance Policy Guide 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.

(B) 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 this CPG and reissue it in draft form to allow for pharmacists, veterinarians and patients to comment on its provisions before it is implemented.

Sincerely



Jim Gillespie R. Ph.
Rep
Compounding Pharmacist

CC Senators Shelby & Sessions

Rep. Cramer *Conrad* *Murk*

McClintock

Jim Darling, R.Ph.
1303 McLain
Newport, Arkansas 72112
870.523.5888
jndarling@earthlink.net

29 January 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,

As a pharmacist, I was very saddened to learn of the FDA's ban on veterinary compounding through the Compliance Policy Guide, particularly without allowing comments violating FDA Good Guidance Practices. Professionally, our basic rights and privileges have been taken away from us.

From time to time my local vet has asked me to make some specialized prescriptions for small animals. I feel that these prescriptions added to the quality of life of those animals that otherwise they might not be able to enjoy. Safety and wellbeing for these animals was never compromised. The vet and pet owners were all satisfied as well. Compounding for non-food producing animals from bulk substances in a fundamental pharmacy right.

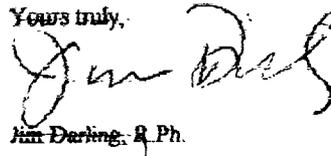
As a former livestock producer, I am always concerned with ill animals entering the food chain. There are many drugs available for veterinary use without any supervision for large animals. Why should compounding pharmacists be penalized? We are all one the same team and would like to participate on the team and do our part to help. Small animals should be exempted from this ban as well.

May I offer as a suggestions for public safety that the food and supplements fed to large animals be regulated and certain additives banned. It is also very important to label the country of origin for all food and especially meat products.

Please reconsider your position on the CPG by withdrawing and reissuing it in draft form to allow pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Your consideration is appreciated in this matter.

Yours truly,



Jim Darling, R.Ph.

cc: Mark McClellan, FDA Commissioner
Congressman Marion Berry
IACP

TABOR DRUG, INC.
224 SOUTH MAIN STREET
LINDSAY, OK 73052
405-756-3222 FAX 05-756-2861

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

Dear Sir

I am writing this letter to comment on CVM Compliance Guide (CPG) in its 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.

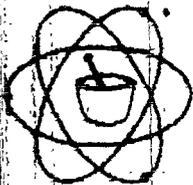
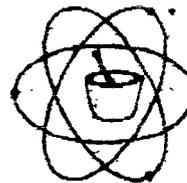
In my practice I observe the State Board of Pharmacy, which has guidelines for compounding veterinary prescriptions for non-food producing animals from bulk powders. The way the CVM's CPG is written it would be illegal to compound any prescription from bulk powders. Therefore, trying to meet the needs of my local veterinarian and his patients would cause extreme hardship and undue suffering for many classes of non-food animals. The unequal enforcement of the CPG by the FDA leaves a pharmacist in the dark as whether to compound or not. It puts the pharmacist in a difficult position either breaking the law and, or neglecting the patients pets and giving the veterinarian a problem as to how he can best serve his patient. This puts the pharmacist in a bad light to his patients and it is difficult to explain why I may compound for the human needs but let the animals suffer because I cannot violate a federal law without endangering my right to practice my profession.

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

Sincerely,


Kohon H. Tabor, D. Ph., Vice President

Jan. 31, 2004

**WYOMING PARK PHARMACY***Specializing in customized medications*

2301 Lee S.W. • Wyoming, Mt. 49509
616-532-2361 Fax 616-532-8122

February 4, 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 to express concerns I have with the Compliance Policy Guide that was issued in final form. There are some requirements in this CPG that are a problem. I believe that there needs to be a comment period before this is put into effect. One prohibition in the CPG ~~against compounding from bulk active ingredients~~ is extremely problematic. It is essential that pharmacist be able to compound for **non-food producing animals** from bulk substances. There are many instance where using a bulk chemical is necessary. For an example, using Potassium Bromide for treating seizures in canines. With out the ability to use these pure chemicals, many pets would suffer, or have no choice but to be euthanized.

I believe it would be in everyone best interest for the FDA to withdraw the CPG. It should be reissued in a draft form to allow for veterinarians, pharmacists, and patients to comment on it, before it is implemented.

Sincerely,

Paul Jensen R.Ph.
Compounding Pharmacist

Cc FDA Commissioner Mark McClellan M.D. Ph.D.
Senator Debbie Stabenow
Senator Carl Levin
Representative Vernon Ehlers
International Academy of Compounding Pharmacist

Your Partner in Health Care



MOSS PHARMACY AND NUTRITION CENTER

R T ("TENNY") MOSS, JR
PHARMACIST - CHEMIST

804-E WEST SECOND LOOP ROAD
FLORENCE, SC 29505
PHONE 843 665 0289
FAX 843 667-9964

May 26, 2004

Lester Crawford,
Acting FDA Commissioner
Washington, DC
FAX 301-443-3100

VIA FAX

Dear Commissioner Crawford:

I am a pharmacist who uses bulk drug ingredients to make medicines for companion and non-food grade animals. I respectfully ask you on behalf of the FDA to withdraw the CPG issued in July, 2003 that disallows compounding with bulk ingredients for animals.

I have copied letters to my Senators and Representatives to you, expressing my concerns about this CPG.

Regards,

A handwritten signature in black ink that reads "Tenny Moss". The signature is written in a cursive, flowing style.

Tenny Moss

**MOSS PHARMACY AND NUTRITION CENTER**R T. ("TENNY") MOSS, JR
PHARMACIST - CHEMIST804-E WEST SECOND LOOP ROAD
FLORENCE, SC 29505
PHONE 843-667-0289
FAX 843 667 9964

May 25, 2004

Representative James Clyburn
Washington, DC
FAX 202-225-2313

Dear Representative Clyburn:

In July, 2003 the Food and Drug Administration issued a Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk drug ingredients. This CPG applies to veterinarians and pharmacists who compound medicine for non-food grade animals.

The FDA issued this CPG in final form, without providing opportunity for any public input. As I understand it, this was done in violation of FDA's own policy and usual practice

The new policy prohibiting veterinarians and pharmacists from using bulk drug ingredients is unreasonable in the extreme. There are no other sources of drug ingredients for many animal prescriptions. I have many dogs with seizure disorders on the drug potassium bromide capsules and liquid. We make their medicine with bulk potassium bromide. I prepare diethylstilbestrol 1mg capsules for dogs with urinary incontinence. The only source for the active ingredient is bulk powder. This past week we made oral suspensions of metronidazole benzoate for dogs, cats, and a bird to treat infections in those pets. The only source for metronidazole benzoate in America is from bulk powder. There are many other occasions when it is necessary to make medicines for companion animals from bulk powder drug sources. We make medicines for people everyday from bulk sources of active ingredients. Where is the logic that prohibits a veterinarian or pharmacist from using bulk ingredients to make medicine for non-food grade animals coming from? It certainly does not come from science or common sense.

If veterinarians and pharmacists are prohibited by the FDA from using bulk ingredients to make medicines for animals, two things will happen: the animals will remain sick or will die

I respectfully ask you to send a letter to the FDA asking that they withdraw the CPG and reissue it in a draft form to allow veterinarians, pharmacists, and owners of veterinary patients to comment on its provisions before it is implemented.

Regards,

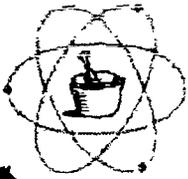
Jenny Moss

Jenny Moss

cc: Lester Crawford,
Acting FDA Commissioner

cc: IACP

Copy Representative John Spratt
Senator Ernest Hollings
Senator Lindsey Graham



Custom Dosing Pharmacy

JEFF BARTON, R.Ph.

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219-662-5602
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1-30-04

Dear Dr. Sundlof,

Your CVM has issued this Compliance Policy Guide in final form without allowing opportunity for comments from all parties involved, 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. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. For example, diethylstilbesterol used for urinary incontinence in dogs, methimazole used for thyroid problems in cats, and cisapride used in many household pets for GI problems. While I do agree we must focus on many illegal drugs being given to animals we consume, I believe that we need to 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 for your time,

Craig Locke R.Ph.

cc: Mark McClellan, FDA Commissioner
cc: Sen R. Lugar
cc: Sen E. Bayh
cc: International Assoc. Compounding Pharmacy



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Thank-you for your time.

Jeff Barton R.Ph.

cc: Mark McClellan, FDA Commissioner
cc: Sen R. Lugar
cc: Sen E. Bayh
cc: International Assoc. Compounding Pharmacy

AIMEE R. GREENBERG, PHARM.D
3371 TURNBERRY CIRCLE
CHARLOTTESVILLE VIRGINIA 22911
(434) 973-0922

February 2, 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:

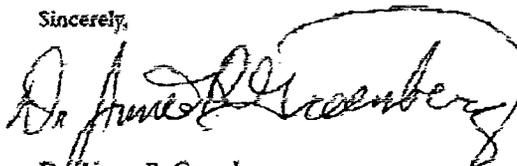
The U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) recently issued a Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients, a standard that is much more restrictive than FDA's policies governing compounding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

CVM issued this Compliance Policy 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. 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 depends on 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 patients to comment on its provisions before it is implemented.

Sincerely,



Dr. Aimee R. Greenberg
Clinical Consultant
The Apothecary

cc: Mark McClellan, FDA Commissioner
cc: Senator John Warner
cc: Senator George Allen
cc: Representative Virgil Goode, Jr.
cc: International Academy of Compounding Pharmacists

3371 TURNBERRY CIRCLE • CHARLOTTESVILLE, VA • 22911
PHONE (434) 973-0922 • E-MAIL: AIMEERGREENBERG@AOL.COM

Medical-Dental Pharmacy

689 E. NEES

Fresno, Ca 93720

ph (559)439-1190

fax(559)-439-1655

e-mail mdpil@aol.com

Web www.rxcompounders.com

IN THE SAVE-MART SHOPPING CENTER

September 29, 2003

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

Dear Sir,

I learned today of the Compliance Policy Guide for veterinary compounding that has been instituted by the FDA. We are a large compounding pharmacy and do approximately 10 to 15 compounded prescriptions per day for local veterinarians. We do not currently provide compounding services to vets treating large (food chain) animals..

Compounding in general does one or two specific things. It either allows the preparation of a dose that is not commercially available, or allows the use of a more easily compliant dosage form. If I can give you a few examples, it might help.

- a. Potassium Bromide liquid (for canine seizures)- commercially not available, but used for years in Veterinary Medicine. Recognized in Plum's "veterinary Drug Handbook" with no commercial forms available in the U.S.
- b. Methimazole flavored oral suspension and trans-dermal forms- for feline hyperthyroidism, neither commercially available in the U.S.
- c. Tasteless metronidazole for cats, dogs, snakes, primates (zoo), rabbits, pet rats and pet mice. Commercial products unavailable in U.S.
- d. Penicillamine concentrated drops for metal poisoning in exotic pet birds. Product only available as tablets or capsules commercially, in much too high a dose.
- e. Combination Digoxin, Enalapril, Furosemide flavored (beef, liver, chicken) for dogs with congestive failures.
- f. Cisapride flavored oral suspension for cats, dogs, and rabbits.

FACSIMILE

FAXED
5-20-04

Name: Lester Crawford, Director
Organization: U.S. Food & Drug Administration
Fax: (301) 443-3100
Phone:
From: Timothy U. Wright, RPh
Date: 05/20/2004
Subject: Compliance Policy Guide 608.400
Pages: 7

Urgent Reply ASAP Please Comment For Your Records

Comments: We, ardent supporters of pet owners and their veterinarians, are extremely opposed to the final form CPG 608.400 and request that the document be withdrawn and reissued in draft form to allow open hearings on the many concerns involved.

We believe the document was issued outside of correct procedures...without public comment.

Please review copies of faxes sent with regard to this issue to Senators Shelby and Sessions and Representative Bacchus.

cc: IACP

From the desk of..
 Timothy U. Wright, RPh
 Compounding Pharmacist
 Tuscaloosa, AL 35406