

**TIM HOLDEN**

17TH DISTRICT, PENNSYLVANIA

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October 7, 2003

Mr. Amit K. Sachdev  
Associate Commissioner for Legislation  
Food and Drug Administration  
U.S. Department of Health and Human Services  
Parklawn Building  
5600 Fishers Lane, Room 15-47  
Rockville, MD 20857

Dear Mr. Sachdev:

My constituent, Mr. John K. McClellan, has requested my assistance regarding the Compliance Policy Guide on compounding for animals. Mr. McClellan is a pharmacy owner; thus, he understands the actual effect the implementation of these policies causes. Enclosed please find the information that explains the situation in further detail.

Any consideration you can give to the review of this matter and a reply to my district office would be greatly appreciated.

Thank you for your kind assistance in this matter.

Sincerely,

TIM HOLDEN  
Member of Congress

TH/pd

Enclosure

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# Bloomfield Pharmacy, Inc.

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Federal ID 25-1772749

John K. McClellan R.Ph., Pharmacy owner/Compounding Pharmacist  
Bloomfield Pharmacy  
1 West Main St  
P.O. Box 38  
New Bloomfield, PA 17068

October 2, 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 extremely restrictive Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients.

The Center for Veterinary Medicine issued this Compliance Policy Guide in final form without allowing opportunity for comments, 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. The FDA's Prohibition in this CPG against compounding from bulk active pharmaceuticals will cause a plethora of problems. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

This will not only hurt the pharmacy but also the veterinary office and the non- food producing animals we care for. Many medications are not available in a form that animals can take or the strength of the medication might not be available, thus a compound is necessary. Some of the manufactured active pharmaceuticals we could compound with, won't work in a compound for an animal because of being time released, having coating that can't be crushed or in a form where the animal will froth at the mouth because of the bitterness of the commercially available pharmaceutical. This CPG is much more restrictive than the FDA's policies governing compounding for human patients.

I am asking that the FDA withdraws 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,

John K. McClellan R.Ph.  
Pharmacy Owner/Compounding Pharmacist

CC: FDA Commissioner Mark McClellan, MD, Ph.D.  
Senator Rick Santorum  
Senator Arlen Specter  
Rep. Bill Shuster  
Rep. Tim Holden  
IACP