Minnesota Board of Pharmacy

Guidance on the Compounding of Veterinary Products
Approved: March 4, 2015
Updated: October 18, 2017

EXECUTIVE SUMMARY

Board staff has held several meetings with representatives of the Minnesota Veterinary Medical Association to discuss issues involving veterinary drug compounding. Dr. Julia Wilson, Executive Director of the Minnesota Board of Veterinary Medicine, participated in these discussions. Staff presented an analysis and recommendations to the Board at its March 4, 2015 meeting. Based on the staff analysis and recommendations the Board adopted the following position statement:

> The Minnesota Board of Pharmacy will temporarily exercise enforcement discretion by not requiring a pharmacy to become licensed as a manufacturer when it compounds and distributes a limited supply of veterinary products that are **needed in urgent or emergency situations**; where the health of an animal is threatened, *or* where suffering or death of the animal is likely to result, from failure to treat.

The Board issues the following guidance, pursuant to MN Stats. §214.108, which states that a "health-related licensing board may offer guidance to current licensees about the application of laws and rules the board is empowered to enforce." Note that this guidance will remain in effect only until the Board can promulgate appropriate rules related to this issue.

1. Pharmacies licensed by the Board can already compound and dispense drugs, pursuant to a patient-specific prescription received in advance of the dispensing, provided that such compounding and dispensing is done according to MN Stats. §151.253 and the applicable rules of the Board. (Note that only those pharmacies that have selected the non-sterile and/or sterile compounding licensing categories are allowed to compound drugs). *Compounding done pursuant to a patient-specific prescription is **not** the subject of this guidance.*
2. The Board will exercise enforcement discretion and not take action against a pharmacy that, in good faith, provides a compounded drug to a veterinarian, at wholesale and without first receiving a patient-specific prescription, ***only*** when:
    a. The compounded drug is needed to treat animals in urgent or emergency situations; that is, where the health of an animal is threatened, or where suffering or death of an animal is likely to result, from failure to treat.
    b. Timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.
    c. There is no FDA-approved, commercially manufactured drug that is suitable for treating the animal; or there is a documented shortage of such drug.
    d. The compounded drug is to be administered by a veterinarian or a bona fide employee of the veterinarian; or dispensed to a client of a veterinarian in an amount not to exceed what is necessary to treat an animal for a period of ten days.
    e. The pharmacy is licensed by the Board as a drug wholesaler. (Except that a pharmacy may distribute compounded drugs as described in this guidance until June 1, 2015 without being licensed as a drug wholesaler).
    f. The pharmacy has selected the sterile or non-sterile compounding licensing category.
    g. The pharmacy is appropriately registered by the United States Drug Enforcement Administration when providing compounded products that contain controlled substances.

BACKGROUND

Board staff has met several times over the past two years with representatives of the Minnesota Veterinary Medical Association (MVMA). The meetings focused on the compounding of veterinary products. Dr. Julia Wilson, the Executive Director of the Minnesota Board of Veterinary Medicine, has participated in these discussions. The MVMA is concerned because most pharmacies that produce veterinary drug products are no longer willing to provide veterinarians with drugs that are compounded for "office use". Board staff explained to the MVMA representatives that a prohibition against compounding for "office use" has been in place in Minnesota for a very long time – and one *possible* reason that compounding pharmacies are no longer distributing drugs for "office use" is that they are being particularly diligent in following federal and state laws in the aftermath of a recent public health crisis involving the distribution of contaminated compounded products.

The Board has also recently received numerous petitions from veterinarians about this issue. Staff has determined that this petition drive was orchestrated by an out-of-state pharmacy that specializes in veterinary compounding. In the opinion of staff, the petitions contain potentially incomplete and/or misleading information.

For example, one version contains the statement "The Drug Quality and Security Act signed into law in 2013 addressed these unique challenges and purposely excluded veterinary medicine – and for a good reason." However, the FDA adopted regulations under another federal law, the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), which do apply to the compounding of animal drugs. In addition, the FDA has interpreted the Food, Drug and Cosmetic Act (FDCA) to make no distinction between the compounding and manufacturing of a drug. The position of the FDA appears to be that neither the FDCA "nor its implementing regulations exempt veterinarians or pharmacists from the approval requirements in the new animal drug provisions of the Act, 21 U.S.C. Section 360b." The petitions also fail to mention that the FDA has issued a Compliance Policy Guide concerning *Compounding of Drugs for Use in Animals*. (From which the above quoted statement is taken).

The American Veterinary Medical Association has issued a policy statement on compounding, which is included as Appendix A. As mentioned above, the U.S. Food and Drug Administration has issued a Compliance Policy Guide for *Compounding of Drugs for Use in Animal* (FDA CPG), which is included as Appendix B.

Board staff presented the following analysis to the Board at its March 4, 2015 meeting.

Analysis

Federal Considerations

The FDA CPG contains the following statement (emphasis added):

> 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. Furthermore, *FDA regulations specifically permit the compounding of products from approved animal or human drugs under the conditions set forth in 21 CFR 530.13. This activity is not the subject of this guidance.*

Thus the FDA CPG does ***not*** address compounding that is done pursuant to a prescription issued for a specific animal in advance of the dispensing of a drug. (As noted below, state laws and rules also allow pharmacies to compound and dispense drugs after receiving a prescription for a specific patient). However, the FDA CPG also contains this statement (emphasis added):

> "FDA is greatly concerned about veterinarians and pharmacies that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act (e.g., compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product). These activities are the focus of this guidance. *Pharmacies and veterinarians who engage in activities analogous to manufacturing and distributing drugs for use in animals may be held to the same provisions of the Act as manufacturers.*"

The FDA CPG includes the following policy (emphasis added):

> "Generally, FDA *will defer to state authorities regarding the day-to-day regulation of compounding* by veterinarians and pharmacists of animal and human drugs that are intended for use in animals.
>
> . . .
>
> However, when the scope and nature of activities of veterinarians and pharmacists raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new animal drug, adulteration, or misbranding provisions of the Act, FDA has determined that it will seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the veterinarian or pharmacist engages in any of the following acts:
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> 1. *Compounding of drugs for use in situations (a) where the health of the animal is* ***not*** *threatened; and (b) where suffering or death of the animal is* ***not*** *likely to result from failure to treat.*
>
> . . .
>
> 7. Compounding drugs for third parties who resell to individual patients, or *offering compounded drug products at wholesale to other state licensed persons* or commercial entities *for resale.*
> 8. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.
> 9. Compounding of drugs for use in animals where an approved new animal drug or approved new human drug used as labeled or in conformity with 21 CFR Part 530 will, in the available dosage form and concentration, appropriately treat the condition diagnosed.

State Considerations

Until July 1, 2014, compounding for "office use" was not allowed at all in Minnesota – pharmacies were allowed to compound drugs only pursuant to prescriptions for specified patients received in advance of the dispensing. However, investigations have revealed that many businesses licensed only as pharmacies were illegally distributing drugs at wholesale for "office use." The Board of Pharmacy sought changes in the sections of statutes related to compounding in 2013 and 2014. Partially in response to concerns

expressed by veterinarians, the Board sought the following change, which the Legislature enacted (emphasis added):

> MN Stats. §151.253**.** Compounding. Subdivision 1. Exemption from manufacturing licensure requirement. Section 151.252 shall not apply to:
> (1) a practitioner engaged in extemporaneous compounding, anticipatory compounding, *or compounding not done pursuant to a prescription drug order when permitted by this chapter or the rules of the board*; and
> (2) a pharmacy in which a pharmacist is engaged in extemporaneous compounding, anticipatory compounding, *or compounding not done pursuant to a prescription drug order when permitted by this chapter or the rules of the board*.

This language became effective on July 1, 2014. The italicized portion authorizes the Board to engage in rule-making for the purpose of specifying the conditions under which a business licensed only as a pharmacy can compound without first receiving a patient-specific prescription. The Board has not yet had the time and resources to engage in such rule-making. Since the Board has not yet promulgated rules in this area, compounding for "office use" is still not permitted in Minnesota.

Concerns of the MVMA and Veterinarians

The essence of these concerns is found in the following excerpt from the AVMA Statement on Veterinary Compounding (emphasis added):

> "It is not legal for compounded preparations to be developed in large quantities and sold to third parties (including veterinarians and companies) or wholesalers for resale to individual patients. However, *the AVMA asserts veterinarians should be able to legally maintain sufficient quantities of compounded preparations in their office for* ***urgent administration needs or emergency situations***.

The MVMA would like the Board to take action to allow businesses licensed as pharmacies (rather than manufacturers) to supply limited amounts of drugs for office use in those situations where the health of an animal would be threatened if immediate treatment is not given or where the animal is likely to suffer or die as a result of failure to treat.

Executive Director Recommendation

In the FDA CPG, the FDA appears to clarify that it interprets federal laws and regulations to prohibit a pharmacy from compounding for "office use" in most circumstances. However, the FDA also seems to indicate that it will exercise enforcement discretion when such compounding is done for situations in which the health of an animal is threatened or the animal might die or suffer unless immediate treatment is given. These situations can occur if there is no FDA-approved, commercially manufactured drug that veterinarians can purchase and use. One example is apomorphine, a drug used for dogs to treat suspected poisoning. It must be given as soon as possible after the suspected ingestion of a poison, but it is no longer commercially available.

The Executive Director recommends that the Board go on record as stating that it will *temporarily* exercise enforcement discretion by not requiring a pharmacy to become licensed as a manufacturer when it compounds and distributes a limited supply of veterinary products that are needed in urgent or emergency situations; where the health of an animal is threatened and where suffering or death of the

animal is likely to result from failure to treat. If the Board decides to exercise this enforcement discretion, staff will work with the MVMA to develop a limited list of drugs to which this discretion would apply.

Assuming that the Board decides to exercise this enforcement discretion, staff will continue to seek clarification from the FDA about its interpretation of relevant federal statutes and regulations. Assuming that, as it states in its CPG, the FDA "will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals", the Board should consider promulgating rules that formally allow compounding for office use in the very limited circumstances outlined above.

GUIDANCE

The Board issues the following guidance, pursuant to MN Stats. §214.108, which states that a "health-related licensing board may offer guidance to current licensees about the application of laws and rules the board is empowered to enforce." Note that this guidance will remain in effect only until the Board can promulgate appropriate rules related to this issue.

1. Pharmacies licensed by the Board can already compound and dispense drugs, pursuant to a prescription received in advance of the dispensing, provided that such compounding and dispensing is done according to MN Stats. §151.253 and the applicable rules of the Board. (Note that only pharmacies that have selected the non-sterile and/or sterile compounding licensing categories are allowed to compound drugs). *Compounding pursuant to a patient-specific prescription is **not** the subject of this guidance.*
2. The Board will exercise enforcement discretion and not take action against a pharmacy that, in good faith, provides a compounded drug to a veterinarian, at wholesale and without first receiving a patient-specific prescription, ***only*** when:
    a. The compounded drug is needed to treat animals in urgent or emergency situations; that is, where the health of an animal is threatened, or where suffering or death of an animal is likely to result, from failure to treat.
    b. Timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.
    c. There is no FDA-approved, commercially manufactured drug that is suitable for treating the animal; or there is a documented shortage of such drug.
    d. The compounded drug is to be administered by a veterinarian or a bona fide employee of the veterinarian; or dispensed to a client of a veterinarian in an amount not to exceed what is necessary to treat an animal for a period of five days.
    e. The pharmacy is licensed by the Board as a drug wholesaler. (Except that a pharmacy may distribute compounded drugs as described in this guidance until May 1, 2015 without being licensed as a drug wholesaler).
    f. The pharmacy has selected the sterile or non-sterile compounding licensing category.
    g. The pharmacy is appropriately registered by the United States Drug Enforcement Administration when providing compounded products that contain controlled substances.

APPENDIX A

American Veterinary Medical Association Statement on Veterinary Compounding

Compounding, consistent with the Food and Drug Administration (FDA) Extra-Label Drug Use regulations, is the customized manipulation of an approved drug(s) by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a particular patient. Common examples of appropriate compounding in veterinary practice are mixing two injectable drugs, preparing an oral paste or suspension from crushed tablets or adding flavoring to a drug. Compounded preparations are required to be prepared from FDA-approved animal or human drugs. The FDA and federal courts have held that federal drug laws prohibit compounding from bulk chemicals or raw pharmaceutical ingredients as such compounds are unapproved new animal drugs. For more information on compounding from bulk drugs, see AVMA policies on "Compounding from Unapproved (Bulk) Substances in Food Animals" and "Compounding from Unapproved (Bulk) Substances in Non-Food Animals."

Compounded preparations are not equivalent to generic drug products. Generic drug products are FDA-approved, which requires a demonstration of bioequivalence of safety and efficacy with the pioneer FDA-approved drug product. Generic animal drug products are identified by an Abbreviated New Animal Drug Application (ANADA) number on their label or in FDA drug references. In contrast to generic drugs, compounded preparations lack FDA approval.

Veterinarians need to be aware that compounding, including formulation in a novel drug delivery system (e.g. transdermal), may impact the pharmacokinetics of a drug. This may result in drug concentrations that are above or below the therapeutic range and lead to the development of an adverse drug event, including therapeutic failure. In order to minimize the risk of adverse events associated with compounded preparations, the following actions are recommended:

1. The decision to use a compounded preparation should be veterinarian (not pharmacist) driven, and occur within a veterinarian-client-patient relationship. The veterinarian should make that decision utilizing evidence-based medicine.
2. Compounding should be implemented in compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide 608.400 titled "Compounding of Drugs for Use in Animals." Use of compounded preparations in food animals may have food safety concerns that preclude their use unless information exists to assure avoidance of violative drug residues.
3. Use of a compounded preparation should be limited to:
   a. Those individual patients for which no other method or route of drug delivery is practical; or
   b. Those drugs for which safety, efficacy, and stability have been demonstrated in the specific compounded form in the target species; or
   c. Disease conditions for which a quantifiable response to therapy or drug concentration can be monitored.
4. Use of a compounded preparation should be accompanied by the same precautions followed when using an approved drug, which include counseling of the client regarding potential adverse reactions, including therapeutic failure, and attention to the potential for unintended human or animal exposure to the drug. Further, clients should be informed that the compounded preparation has not

been evaluated by the FDA for potency, purity, stability, efficacy or safety, and client consent should be obtained.

a. Veterinarians should report suspected adverse events including therapeutic failure and quality defects involving compounded preparations to the compounding pharmacist, the State Board of Pharmacy and the FDA Center for Veterinary Medicine. Instructions for reporting adverse events to FDA can be found at the FDA website. Pharmacists should instruct pet owners to contact both the prescribing veterinarian and pharmacist immediately if a compounded preparation is associated with an adverse event, including therapeutic failure, and quality defects.

5. Veterinarians should comply with all aspects of the federal extralabel drug use regulations including record-keeping and labeling requirements and urge compounding pharmacies to do the same. The compounded preparation should be labeled that it is not FDA approved.

It is not legal for compounded preparations to be developed in large quantities and sold to third parties (including veterinarians and companies) or wholesalers for resale to individual patients. However, the AVMA asserts veterinarians should be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations.

Advertising and promotional material from the compounding pharmacy should not be interpreted as FDA assurance of proven efficacy, safety or quality.

One element in evaluating the quality of a compounded preparation is whether the compounding procedure follows the guidelines of the United States Pharmacopeia (USP). These guidelines can be found in Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations, USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations, and specific USP drug monographs if available. The USP general chapters and drug monographs define good compounding practices and provide information about compounded preparations that have acceptable strength, quality, purity, and stability to minimize patient harm due to lack of sterility, excessive bacterial endotoxins, and content errors.

Another element in evaluating the quality of a compounding pharmacy is whether the pharmacy is accredited by an independent accreditation body. For example, the Pharmacy Compounding Accreditation Board (PCAB) offers accreditation to compounding pharmacies that meet high quality and practice standards. Further information and a listing of PCAB-accredited pharmacies are available at www.pcab.org. Be aware that independent accreditation is different from association or professional training center memberships that may lack quality assurance programs and inspections.

AVMA advocates for quality assurance oversight of all compounded preparations to ensure that these preparations are prepared and evaluated in a manner consistent with current potency, purity and stability standards.

APPENDIX B

CPG Sec. 608.400 Compounding of Drugs for Use in Animals

Sec. 608.400 - Compounding of Drugs for Use in Animals (CPG 7125.40)

PDF[1], 140kb

This compliance policy guidance is intended to provide guidance and instructions to FDA staff, industry, and the public for obtaining information to help fulfill the Agency's plans regarding the compounding of drugs for use in animals. The compliance policy guidance does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. It is intended for FDA personnel, industry, and the public and is available electronically to the public.

INTRODUCTION

This document provides guidance to drug compounders, veterinarians, and the staff of the Food and Drug Administration (FDA) on how the Agency intends to address compounding of drugs intended for use in animals. This guidance describes FDA's current thinking on what types of compounding might be subject to enforcement action.

BACKGROUND

FDA announced the availability of Compliance Policy Guide (**CPG**) section 608.400 entitled "Compounding of Drugs for Use in Animals" on July 3, 1996 (61 FR 34849), to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. There is a potential for causing harm to public health and to animals when drug products are compounded, distributed, and used in the absence of adequate and well-controlled safety and effectiveness data or adherence to the principles of contemporary pharmaceutical chemistry and current good manufacturing practices. Use of compounded drugs in animals can result in adverse reactions and animal deaths. Furthermore, because the pharmacokinetics and depletion times for residues from compounded products intended for use in food-producing animals are not known, the assignment of an extemporaneous withdrawal time may result in potentially harmful residues in food. Inactive ingredients, such as excipients and vehicles, from unapproved or unknown origins may also pose additional risk (e.g., Freunds adjuvant, a carcinogen).

FDA is updating this guidance to be consistent, to the extent practicable, with the scope of compounding permitted under regulations implementing the Animal Medicinal Drug Use Clarification Act of 1994, to describe what factors FDA will consider in exercising its enforcement discretion regarding compounding of drugs intended for use in animals, and to

ensure the consistency of its policies with regard to compounding of drugs intended for use in humans and in animals.

DISCUSSION

The Federal Food, Drug, and Cosmetic Act (**the Act**) does not distinguish compounding from manufacturing or other processing of drugs for use in animals. FDA acknowledges the use of compounding within certain areas of veterinary practice. 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. Furthermore, FDA regulations specifically permit the compounding of products from approved animal or human drugs under the conditions set forth in 21 CFR 530.13. This activity is not the subject of this guidance.

However, FDA is greatly concerned about veterinarians and pharmacies that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act (e.g., compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product). These activities are the focus of this guidance. Pharmacies and veterinarians who engage in activities analogous to manufacturing and distributing drugs for use in animals may be held to the same provisions of the Act as manufacturers.

With regard to compounding from bulk drug substances, two Federal Appeals Court decisions, United States v. Algon Chemical Inc., 879 F.2d 1154 (3d Cir. 1989) and United States v. 9/1 Kg. Containers, 854 F.2d 173 (7th Cir. 1988), affirmed the FDA position that the Act does not permit veterinarians to compound unapproved finished drug products from bulk drug substances, unless the finished drug is not a new animal drug. The principle established by the court applies equally to compounding by pharmacists.

Neither the Act nor its implementing regulations exempt veterinarians or pharmacists from the approval requirements in the new animal drug provisions of the Act, 21 U.S.C. Section 360b. In the absence of an approved new animal drug application, the compounding of a new animal drug from any unapproved drug or from bulk drug substances results in an adulterated new animal drug in violation of section 21 U.S.C. Section 351(a)(5). The compounding of a new animal drug from an approved human or animal drug also results in an adulterated new animal drug in violation of 21 U.S.C. Section 351(a)(5), unless the conditions set forth in 21 CFR 530.13(b) are met.

DEFINITIONS

1. Bulk drug substance, as defined in 21 CFR 207.3(a)(4), means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

2. Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling
3. A valid veterinarian-client-patient relationship (**valid VCPR**), as defined in 21 CFR 530.3(i), is one in which:
    a. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
    b. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
    c. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

POLICY:

Generally, FDA will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states.

However, when the scope and nature of activities of veterinarians and pharmacists raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new animal drug, adulteration, or misbranding provisions of the Act, FDA has determined that it will seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the veterinarian or pharmacist engages in any of the following acts:

1. Compounding of drugs for use in situations (a) where the health of the animal is not threatened; and (b) where suffering or death of the animal is not likely to result from failure to treat.
2. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving prescriptions issued within the confines of a valid VCPR.
3. Compounding of drugs that are prohibited for extralabel use in food-producing or nonfood-producing animals, under 21 CFR 530.41(a) and (b) respectively, because the drugs present a risk to the public health.
4. Compounding finished drugs from human or animal drugs that are not the subject of an approved application, or from bulk drug substances, other than those specifically addressed for regulatory discretion by the FDA, Center for Veterinary Medicine, e.g., antidotes (see **Appendix A**). Inquiries about compounding from unapproved drugs or

bulk drug substances should be directed to CVM, Division of Compliance, 301-827-1168.

5. Compounding from approved human drugs for which FDA has implemented a restricted distribution system.
6. Using commercial scale manufacturing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients, or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
8. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.
9. Compounding of drugs for use in animals where an approved new animal drug or approved new human drug used as labeled or in conformity with 21 CFR Part 530 will, in the available dosage form and concentration, appropriately treat the condition diagnosed.
10. Compounding from a human drug for use in food-producing animals if an approved animal drug can be used for the compounding.
11. Instances where illegal residues occur in meat, milk, eggs, honey, aquaculture, or other food-producing animal products, and such residues were caused by the use of a compounded drug.
12. Labeling a compounded drug with a withdrawal time established by the pharmacist instead of the prescribing veterinarian.
13. Labeling of compounded drugs without sufficient information, such as withdrawal times for drugs for food-producing animals or other categories of information that are described in 21 CFR 530.12.

The foregoing list of factors is not intended to be all inclusive. Other factors may be appropriate for consideration in a particular case.

REGULATORY ACTION GUIDANCE:

District offices are encouraged to consult with state regulatory authorities to assure coherent application of this guidance to establishments that are operating outside of the traditional practice of pharmacy.

Follow FDA's laws and procedures prior to sharing non-public information with the public, or federal, state, local, and foreign government officials.

FDA-initiated regulatory action may include issuing a warning letter, seizure, injunction, and/or prosecution. Charges may include, but need not be limited to, violations of 21 U.S.C. Sections 351(a)(2)(B), 351(a)(5), 352(a), 352(f)(1), and 352(o) of the Act. Tissue residue violations are covered under 21 U.S.C. Section 342(a)(2)(C)(ii) of the Act.

Issued: 6/26/1996 (7/3/1996 Federal Register)
Revised: 7/8/2003 (7/14/2003 FR)

APPENDIX A

LIST OF BULK DRUG SUBSTANCES FOR COMPOUNDING AND SUBSEQUENT USE IN ANIMALS TO WHICH CVM WOULD NOT ORDINARILY OBJECT

- Ammonium molybdate
- Ammonium tetrathiomolybdate
- Ferric ferrocyanide
- Methylene blue
- Picrotoxin
- Pilocarpine
- Sodium nitrite
- Sodium thiosulfate
- Tannic acid