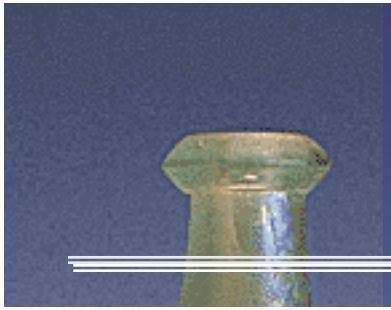
Legal and Ethical Veterinary Compounding

Scott D. Stanley, Ph.D., Professor
University of California, Davis
School of Veterinary Medicine

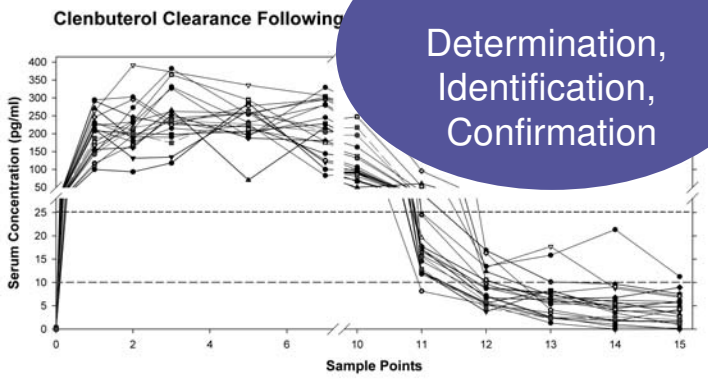
American Association of Equine Practitioners 2009

Equine Chemistry Research



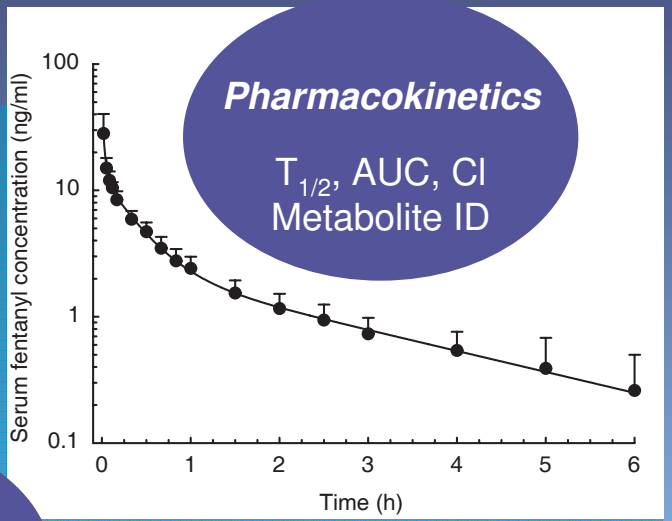
Drug Detection

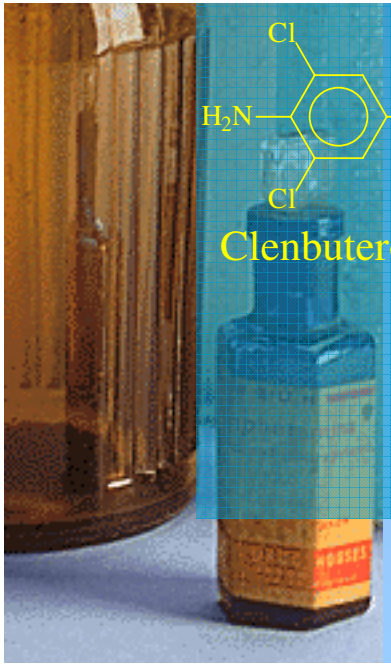
Determination,
Identification,
Confirmation

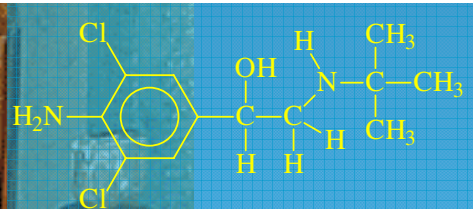


Pharmacokinetics

$T_{1/2}$, AUC, Cl
Metabolite ID



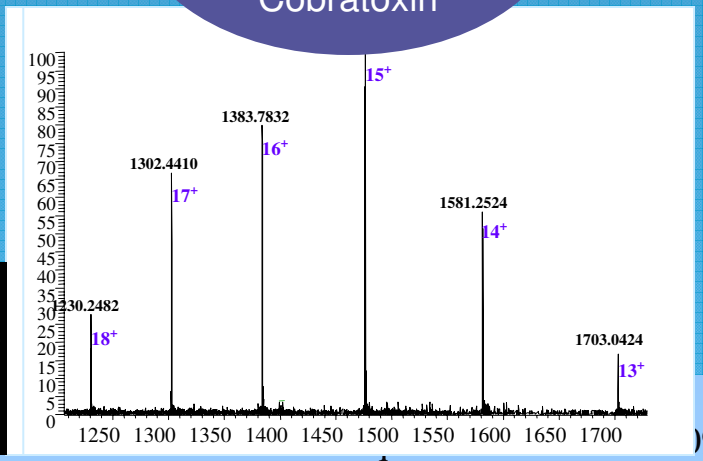




Clenbuterol m/z 240

Proteomics

Erythropoietin,
Growth Hormone,
Cobratoxin



09

Horse Industry Integrity

- Industry Integrity (Perception)
- High Profile Events
  - Triple Crown
  - Breeder's Cup
- Trainer's Livelihood
  - Disqualification
  - Suspension
  - Fine
- Laboratory Reputation

Magical Effects of Drugs/Medications

- Irish mythology: Salmon of knowledge
- Victorian mythology: Alice in Wonderland
- American mythology: Popeye and spinach
- Greek mythology: Diomedes and his mares

Equine Pharmaceuticals:
Manufacturing/ Compounding Issues

AAEP 2009

Definitions

- Integrity – means retention of potency until "beyond use date"
- Potency – means active ingredient strength within ±10% of the labeled amount
- Quality – means the absence of harmful levels of contaminants including filthy, putrid or decomposed substances and absence of active ingredients other than those noted on the label

Compounded Products

- The original Food Drug and Cosmetic Act passed 100 years ago was passed because:
  - At the time almost all drugs available were compounded by pharmacists
  - There were no standards to insure quality and purity
  - There were no standards for efficacy and safety

Available Pharmaceuticals

- FDA-Approved “Pioneer” Drugs
  - For use in the horse
  - For use in other animals
  - For human use
- Generic Drugs
- Compounded Drugs

"Pioneer" Pharmaceuticals

FDA approval process:

- Dosage
- Efficacy
- Safety
- Withdrawal Times (food animals)
- Manufacturing
- Stability
- Labeling
- Packaging
- Advertising
- *Adverse Events*

FDA Approved Drugs: What is Required?

- Drug Efficacy must be demonstrated in two well-controlled trials one of which must be in clinical cases.
- Drug Safety must be demonstrated in one or more studies in the target species
  - acute toxicity study
  - sub-acute toxicity study
  - field safety studies

FDA Approved Drugs: What is Required?

- Manufacturing:
  - All raw materials for drug manufacture must be obtained from an FDA approved source
  - The manufacturing procedure must be described in detail and meet the rigorous standards of FDA's Good Manufacturing Practices (GMP)
  - Stringent testing standards for drug potency and purity must be established

FDA Approved Drugs: What is Required?

- Manufacturing:
  - Stability data must be generated in order to establish the expiration dating
  - Detailed records of each batch of drug produced must be maintained
  - Representative samples of each batch of drugs must be retained for future testing
  - FDA regularly inspects manufacturing facilities

What is a Generic Drug?

- A generic drug is an exact copy of an FDA approved drug that is no longer patent protected.
- All generic drugs are approved by FDA
- Additional efficacy and safety data may be required (e.g., field safety)

“Generic” Pharmaceuticals

FDA approval process:

- *Bioequivalence*
  (and/or)
- *Chemical Equivalence*
- Manufacturing
- Packaging
- Labeling

What is a Generic Drug?

- The requirements for FDA approved raw material sources are the same for a generic drug
- All GMP requirements apply to generic drugs
- All annual reporting requirements are the same as for original drugs

Compounding Pharmacies

Are a necessary and beneficial component of veterinary practice

Compounded drugs…

- ➔ are *not* FDA-approved
- ➔ are *not* generic drugs

Compounded Drugs

- Pharmacy compounding of veterinary drugs has exploded in the past few years

- Allows for DVMs to have formulated
  - Drugs no longer commercially available
  - Drugs not available on animal health market
  - Reformulate drugs into suitable dosage forms

Compounded Drugs

- No regulations on raw material sources
- No quality standards
- No stability data requisite
- Supposed to be a prescription for a specific need in a specific animal (VCPR)
- Bulk compounding is not legal

Compounded Drugs

- It is illegal to compound a specific product when there is an approved drug form of that specific product except to make a different dosing form. However, the approved product must be used to make the compounded new dose form.
- It is illegal to mark up prices on compounded drugs

Compounded Drugs

- *If you use a compounded product, you assume liability for any adverse effects or efficacy failure*
- Drug manufacturers are required to carry product liability insurance
- Pharmacies are not required to carry product liability insurance

Compounded Drugs

- It is illegal to place expiration dating on compounded drug beyond 180 days from preparation
- It is illegal to have a drug compounded in order to obtain the drug at a lower price
- Compounded products are not “generic” forms of approved drug products!

Veterinary Practitioners…

. . . are put in a position of evaluating the integrity of the compounding pharmacy as well as the quality and consistency of the pharmaceuticals they produce!

Concerns:

- Efficacy
- Quality
  - Potency
  - Purity
- Consistency
- Liability

Compounded Drugs

- Little or no ongoing external oversight of:
  - Consistency
  - Quality
  - Potency
  - Bioavailability
  - Sterility
  - Stability
  - Safety
  - Labeling
  - Advertising
  - Adverse Events
- Mainly *self-regulated*

Questions you may want to ask:

- Who is doing the compounding?
  - Often a technician with minimal training
- Where were they trained?
  - Pharmacists - little training in compounding; No training in manufacturing
- Do they use pharmaceutical grade chemicals?
  - Drug companies will not supply
  - Chemicals bought through sources like PCCA are questionable, often produced overseas (e.g., China)

Compounding of Animal Drugs

- >12,000 compounding pharmacies in the United States
  - Most compound veterinary products
  - Many market on the internet
- Big profits to be made
  - Estimated $300 million annually
  - Comprises >20% of animal pharmaceutical industry

Compounding Pharmacy "Best Practices"

California Pharmacy Board

American Association of Equine Practitioners 2009

Compounding by Licensed Pharmacies

- Compounding means work is done under the supervision of a licensed pharmacist.
  - Altering dose form or delivery system
  - Altering the strength of a drug
  - Combining components
  - Preparing a drug product from raw chemicals
- Compounding, does not include, preparation a compounded drug product that is available commercially.

Limitations and Requirements

- No product should be compounded prior to receipt of a valid prescription
- A pharmacy may store a limited quantity of a compounded drug in advance.

Limitations and Requirements

- A “reasonable quantity” of compounded drug product may be furnished to be prescriber for office use.
  - is sufficient for admin. to patients in the prescriber’s office or for distribution of not more than a 72-hr supply to the prescriber’s patients.

Master Formula Record

- Active ingredients to be used
- Inactive ingredients to be used
- Procedure to be used to prepare the drug
- Quality reviews required at each step in preparation of the drug
- Post compounding process
- Expiry dating requirements

Limitation and Requirements

- Where a pharmacy *does not* routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

"This may have prevented the incident in Palm Beach, Florida."

Limitation and Requirements

- The Pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

Limitation and Requirements

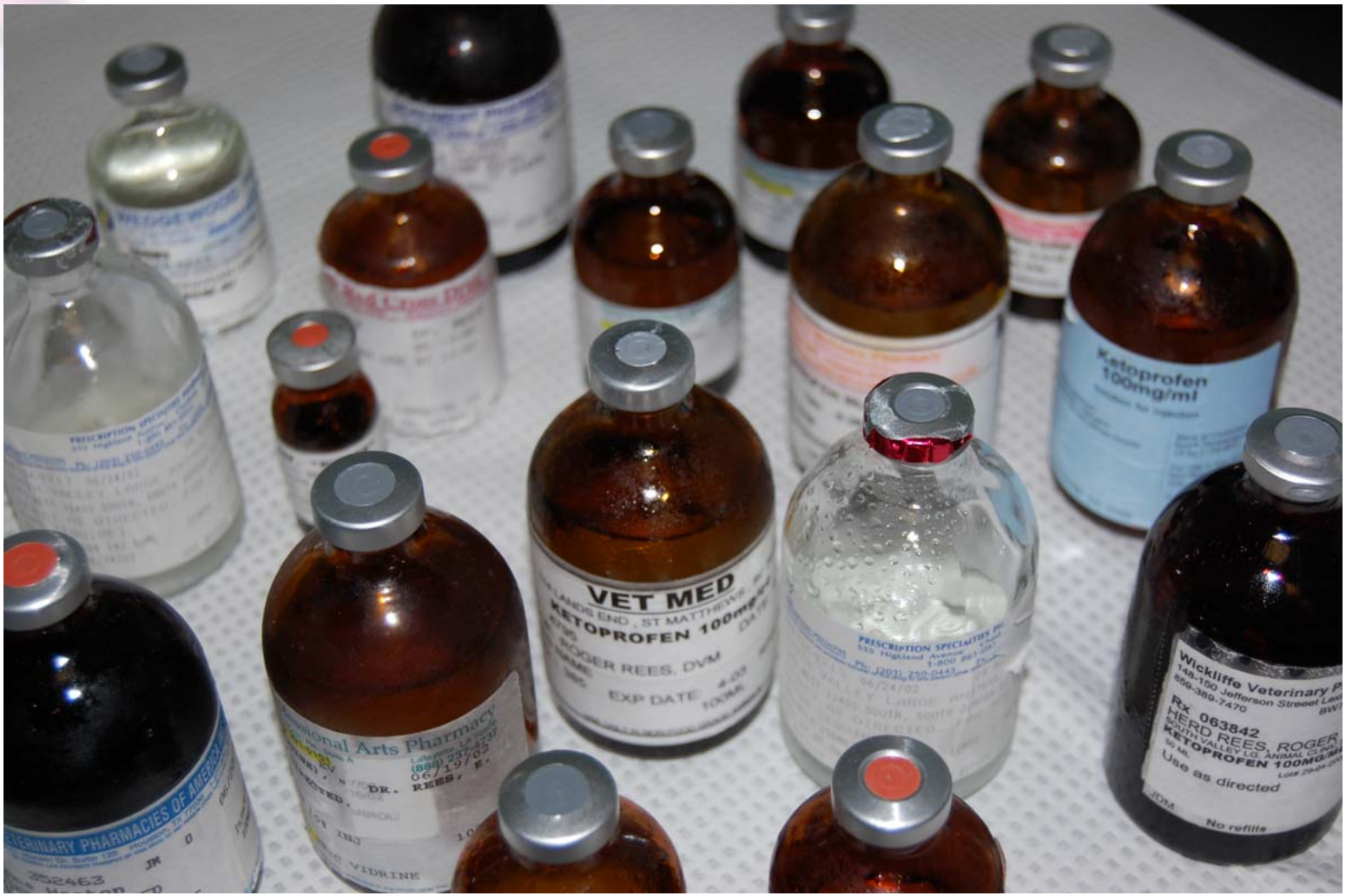
- Every compounded drug product shall be given an use by date representing the date beyond which, in the professional judgement of the pharmacist, it should not be used. The date *shall not exceed 180 days* from preparation.

Records of Compounded Drug Products

- The master formula record
- The date the drug product was compounded
- The identity of the personnel who compounded the drug product
- The identity of the pharmacist reviewing the final drug product
- The quantity of each component used

Comparison for pharmaceutical equivalence of FDA-approved products and compounded preparations of Ketoprofen, Amikacin, and Boldenone

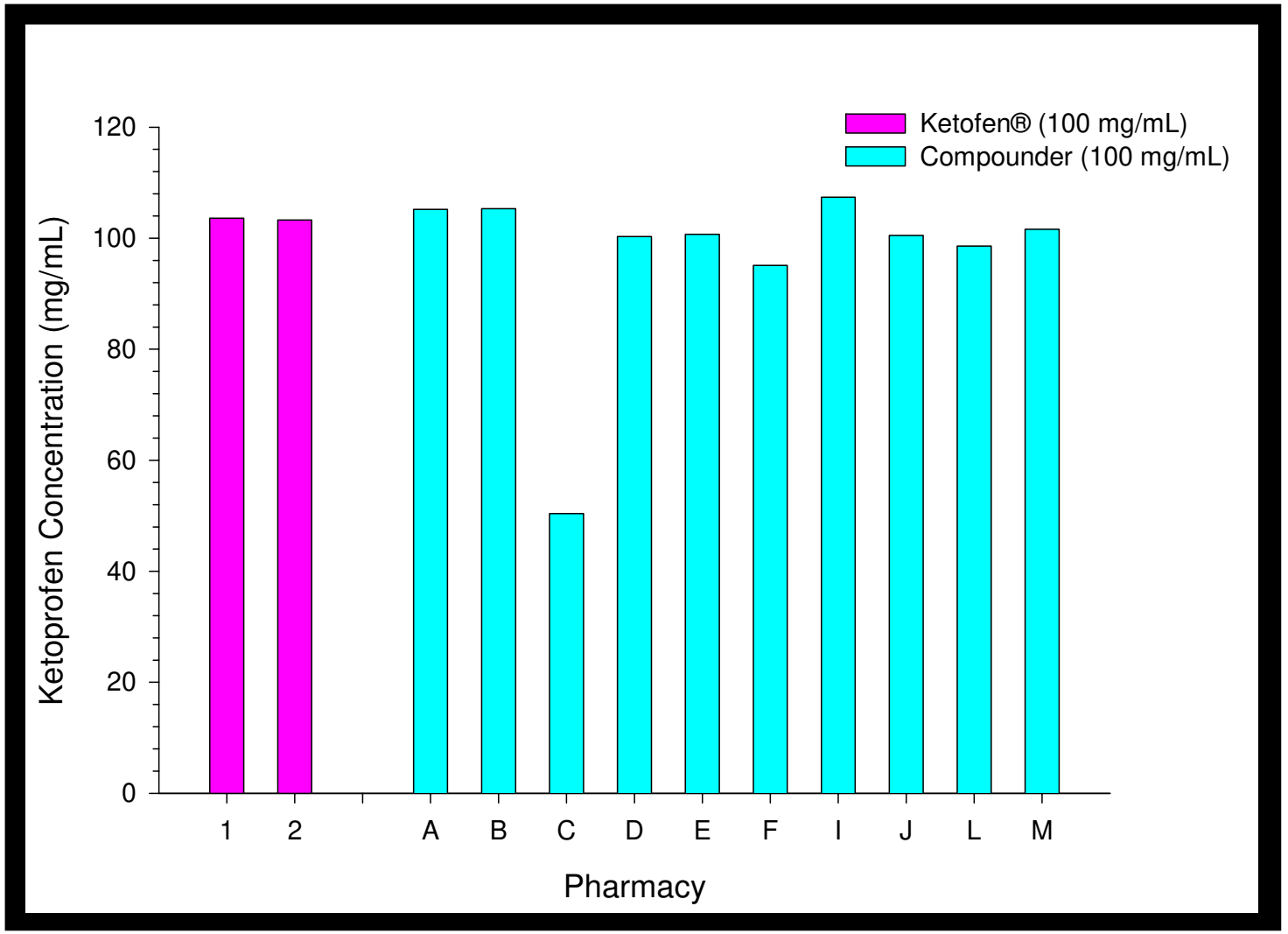
Illegal Veterinary Compounding



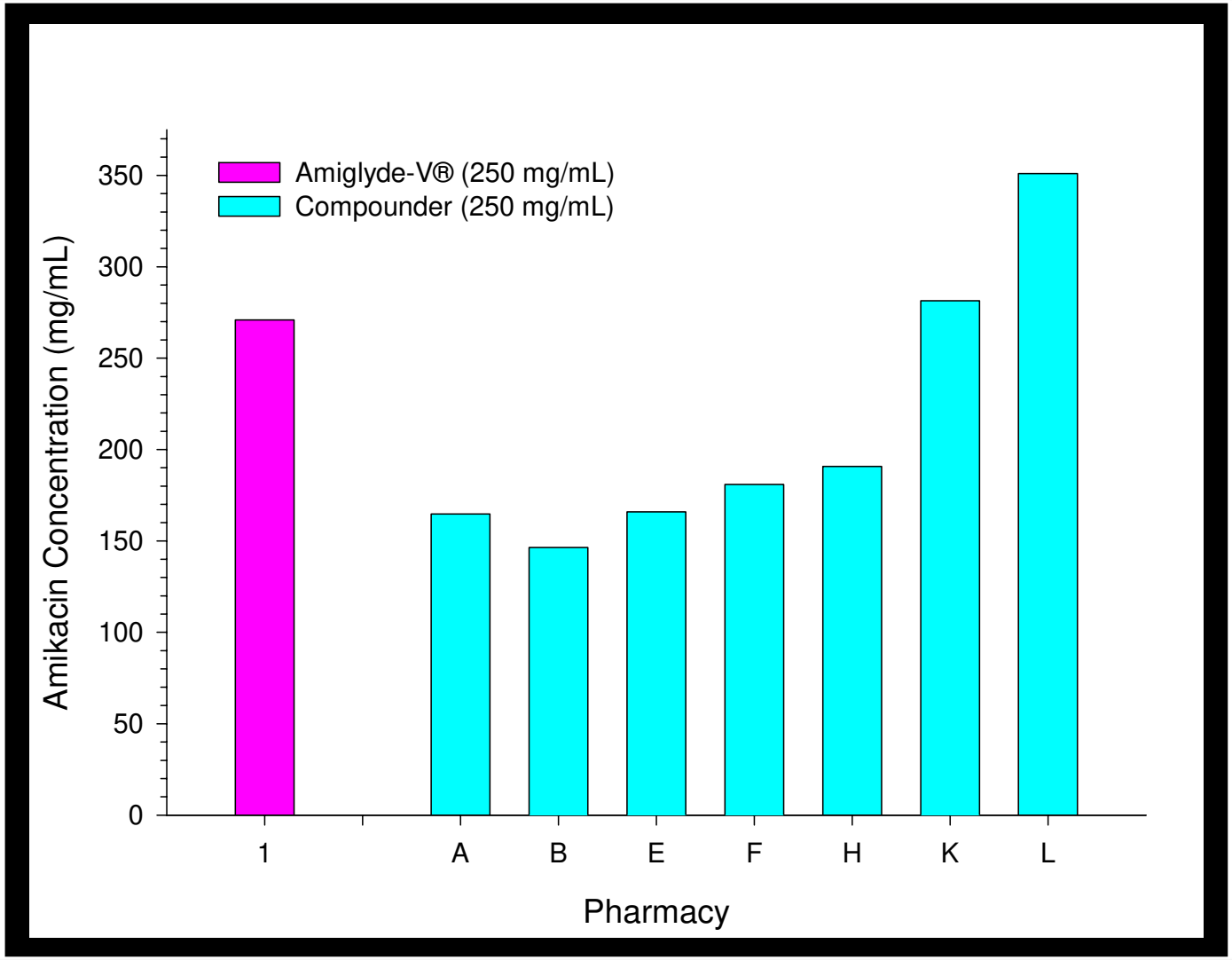
Product Potency

- Ketoprofen (Ketofen®) – stated concentration for all products was 100 mg/ml
- Amikacin (Amiglyde-V®) – stated concentration for all products was 250 mg/ml
- Boldenone (Equipoise®) – stated concentration for was 50 mg/ml for 5 of 6 products tested and 25 mg/ml for the final product

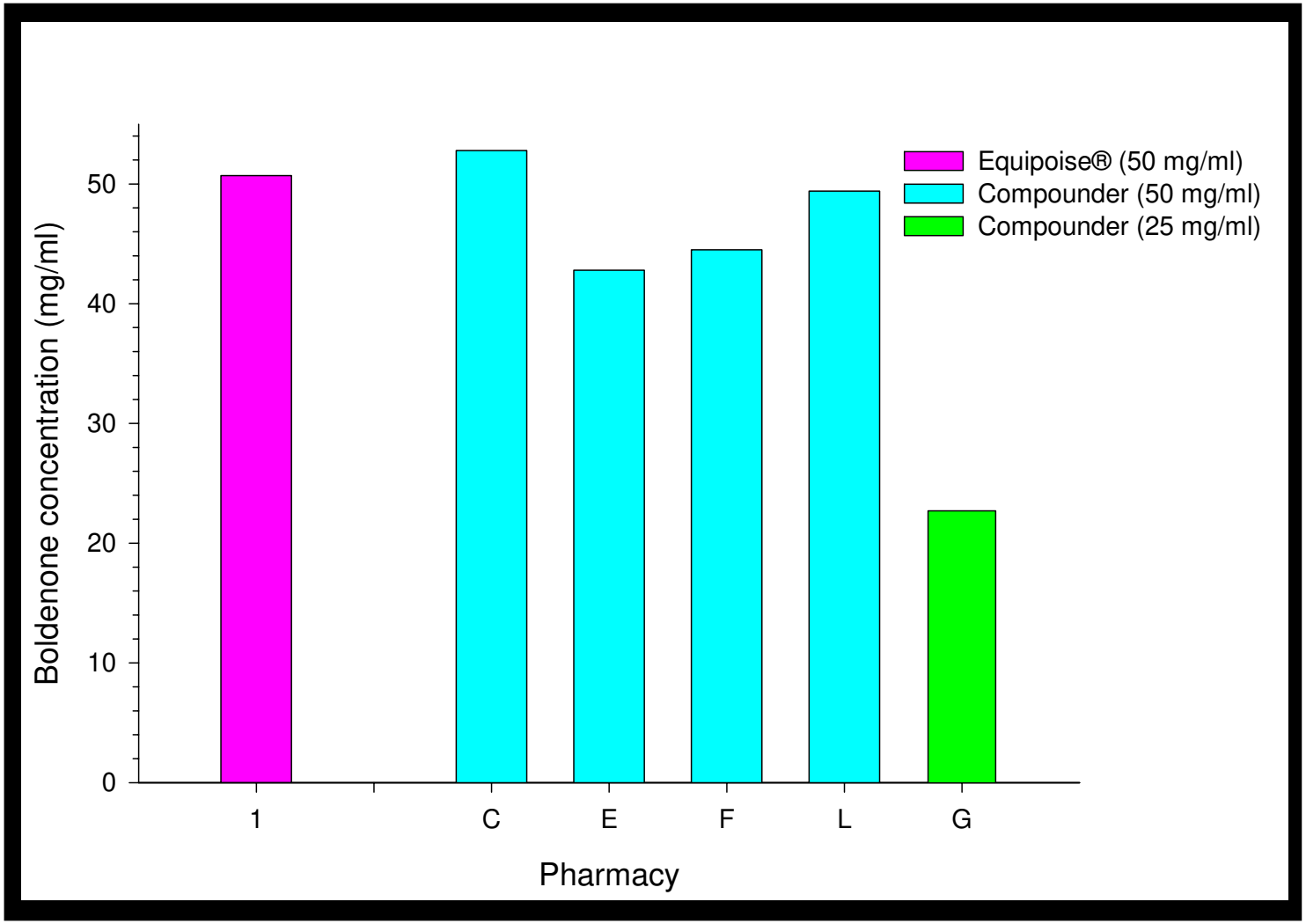
Ketoprofen Potency:



Amikacin Potency:



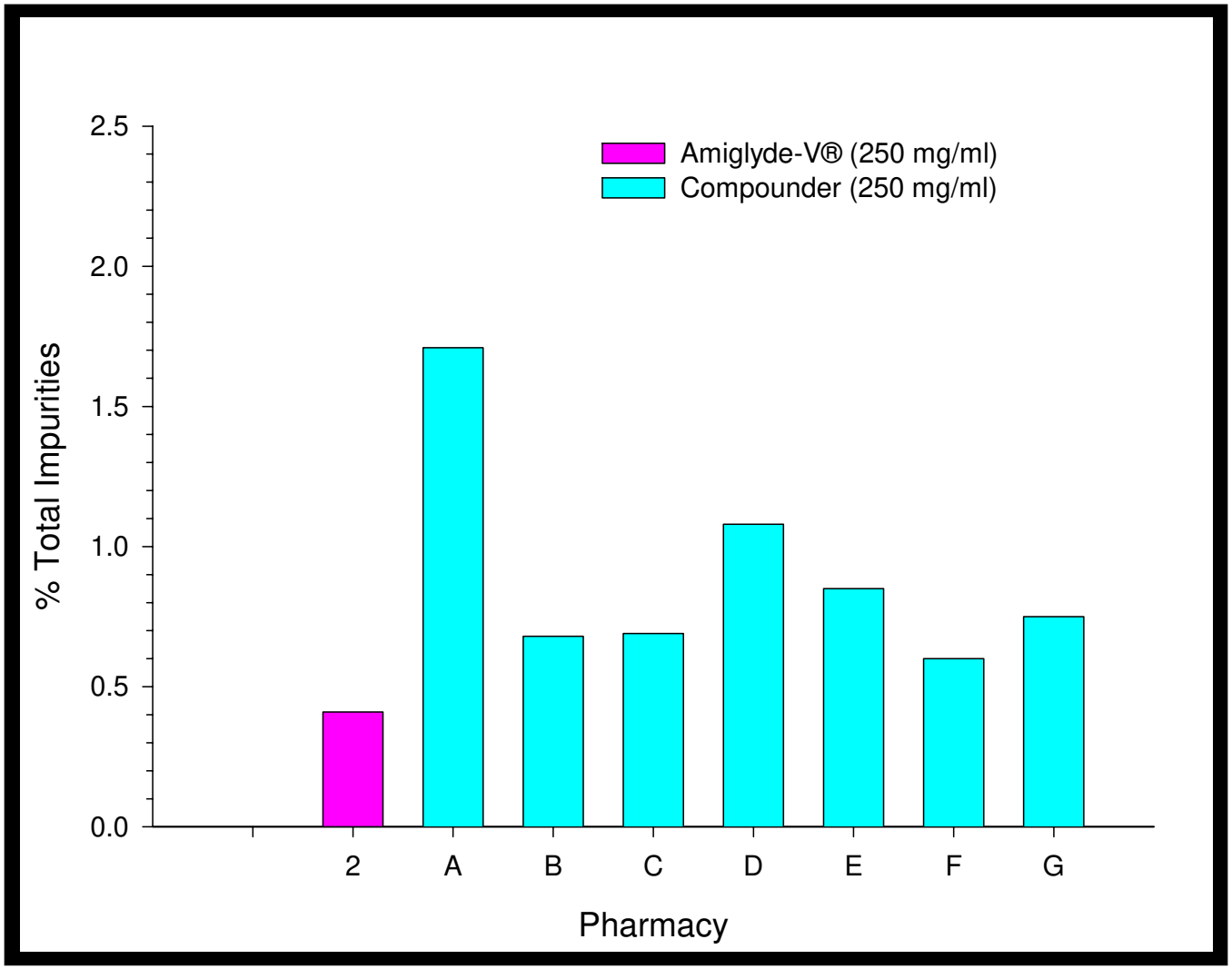
Boldenone Potency:



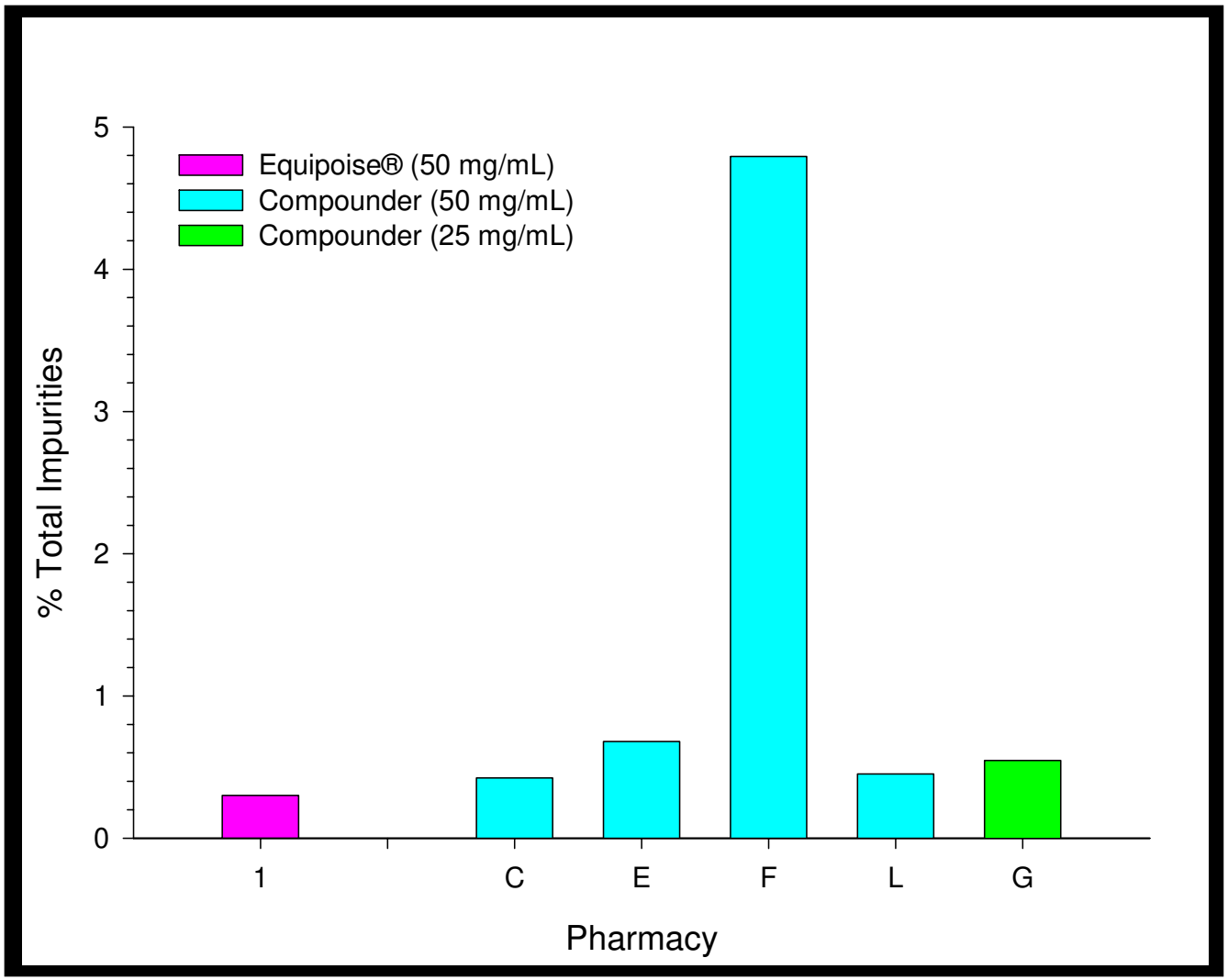
Product Purity

- FDA Criteria for product purity
  - shall not exceed 2.0 total percentage impurity
  - shall not exceed 0.1 percentage single impurity

Amikacin Purity:



Boldenone Purity:



Medical Therapy for Equine Joint Disease: Understanding your Choices?

AAEP 2009

Medical Therapies for Equine Joint Disease

- FDA Approved Animal Drugs
- FDA Approved Generic Drugs
- Compounded Products
- Off-Label Use of Medical Devices as Drugs

FDA Approved Drugs For Equine Joint Disease

- NSAIDs
  - Phenylbutazone, flunixin, ketoprofen, diclofenac
- Corticosteroids
  - Methylprednisolone acetate, triamcinolone acetonide, dexamethasone
- Hyaluronic acid
  - Hylartin-V, Hyvisc, Hylovet, Legend
- PSGAG (Adequan)

Generic Drugs for Equine Joint Disease:

- Phenybutazone
- Flunixin
- Methylprednisolone acetate
- Dexamethasone SP

What is not a Generic Drug

- Compounded Products
  - HA solutions
  - Glucosamine Injection
  - Cocktails (HA, Glucosamine, Chondroitin)
- Medical devices used off label as drugs
  - MAP-5 and Chondroprotec

Well Controlled Study

- Blinded: The person making observations is not aware of treatment group assignment
- Randomized: The subjects are randomly assigned to treatment group
- Standardized: All subjects are treated exactly the same (exercise, feeding, other drugs, etc). The only difference between groups is test drug(s)

Uncontrolled Studies

- Testimonials and uncontrolled studies are especially poor indicators for efficacy
  - Rest and concurrent therapy are usually not controlled
  - The use of other physical and medical therapies are often confounding factors
  - Judgement of efficacy is biased

Compounded Drugs

- Common products compounded for equine joint disease
  - betamethasone suspension
  - acetyl-d-glucosamine injection
  - HA injection
  - “cocktail injections” containing glucosamine, HA and chondroitin

Medical Devices

- There are medical devices for the veterinary field that are being sold and promoted illegally for off-label use to treat equine DJD
  - MAP-5 is an HA solution labeled as a *cryopreservative for semen*
  - Chondroprotec is a solution of chondroitin sulfate labeled as a *topical for wound healing*

Medical Devices

- MAP-5 is not a “generic” form of Legend!
- Chondroprotec is not a “generic” form of Adequan!
- The AAEP has taken the position that it is *unethical* for a DVM to tell a client that one of these medical devices or a compounded drug is a “generic” form of an FDA approved drug

Legal Implications

- A legal expert at the AAEP Convention in New Orleans in 2003 warned:
  - A client cannot consent to substandard practice
  - The fact that the use of compounded drug or the off label use of medical devices is common practice will not constitute a viable defense in a malpractice suit

Veterinarians are Liable!

- No Malpractice Coverage

"There would be an exclusion in a veterinarian's malpractice insurance nullifying coverage if the practitioner were engaged in an *illegal act*, such as the use of a compounded pharmaceuticals from bulk drugs."

AVMA

Palm Beach Polo Ponies

American Association of Equine Practitioner 2009

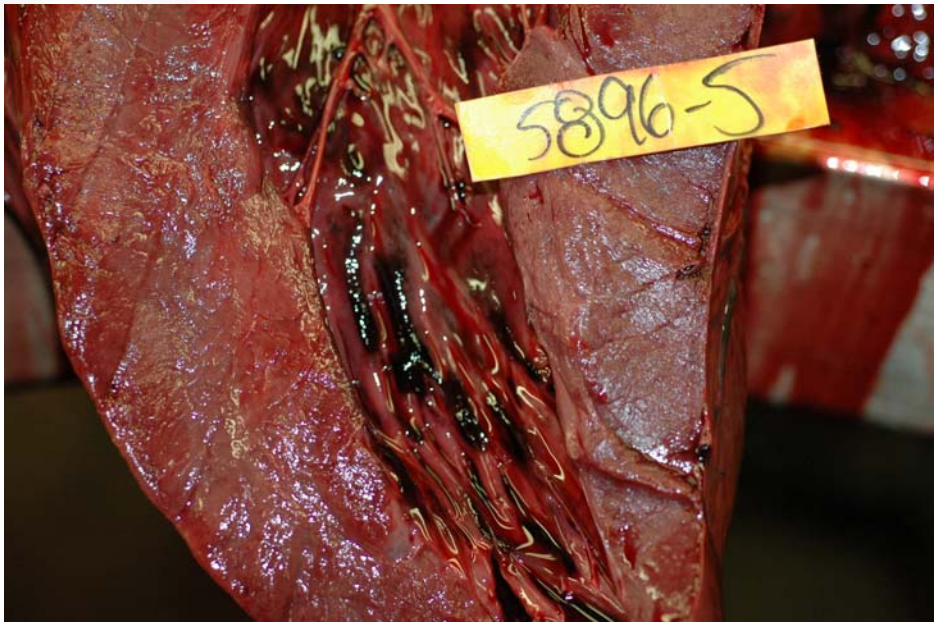
Biodyl® (Merial)

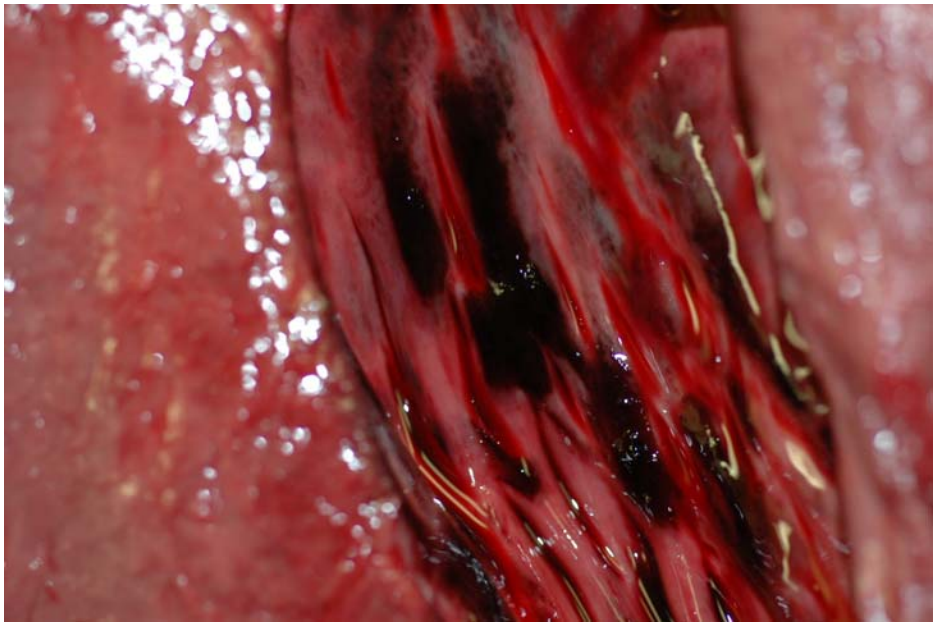
- Each 100 ml contains:
  - Cyanocobalamin (Vitamin B12) 0.05 g
  - Sodium Selenite 100 mg
  - Potassium aspartate semihydrate 1,000 g
  - Magnesium aspartate tetrahydrate 1,500 g
  - Excipient q.s. 100 ml

Compounded Formulation

- Each 100 ml contains:
  - Cyanocobalamin (Vitamin B12) 0.05 g
  - Sodium Selenite ????? mg
  - Potassium aspartate semihydrate 1,000 g
  - Magnesium aspartate tetrahydrate 1,500 g
  - Excipient q.s. 100 ml

Selenium Toxicity





HUMANS ANIMALS

FRANCK'S PHARMACY

Home » Animals » **Quality Assurance**

Quality Assurance

When quality is your main ingredient, you must be sure your compounding Pharmacy is taking extra measures to ensure the best products. Some of Franck's Pharmacy QUALITY ASSURANCE procedures include:

1. Daily temperature and humidity monitoring and documentation
2. Daily refrigerator monitoring and calibration
3. Daily calibration of analytical balances
4. Chemical weight verified by printout
5. Calibration of pH meter before each use on every compounded product
6. Ongoing training, testing and evaluation of aseptic personnel
7. Daily random sterility and pyrogen testing of products
8. Random endotoxin testing of product by independent laboratory
9. Scheduled certification of sterile environment
10. Independent lab testing of air and surface samples for the Cleanrooms
11. Compliance with USP Cleanroom Guidelines for High Risk Compounding
12. Continuous cleaning of compounding environments with alternating cleaning solutions
13. Compounding software with backup for continuous record keeping of:

    A. Formula
    B. Procedure/technique
    C. Lot numbers
    D. Prescription numbers
    E. Expiration dates

14. USP & NF Chemicals obtained from FDA approved suppliers.
15. Regulated storage of raw materials and end products
16. Personnel trained and certified in procedures for each type of aseptic event
17. Personnel dedicated to policies and procedures to ensure a quality product

Rising Star Egg Head Euthanized

by Pete Spanos
Date Posted: July 13, 2005
Last Updated: July 13, 2005

Egg Head, a 3-year-old rising star on the sprint division scene, was euthanized Monday after succumbing to a case of founder.

Trainer Kiaran McLaughlin called the son of Honor Grades "one of the best horses I've ever trained." McLaughlin, speaking from Belmont Park Wednesday, said everything that could have been done to save the colt was.

"He was scheduled for a work two weeks ago Sunday," said the conditioner who also owned a part-interest in the dark bay. "We came into the stall and he was lame, left hind, with a blown-up hock--just out of the blue. That's what started the whole thing.

"We treated him aggressively but it just went right down hill and he foundered. When one founders there are as many causes as cases and it just progressed to the point where we had to put him down."

McLaughlin and a group of several investors purchased a 45% interest in the horse from the colt's main owner, Harvey Clark, after his impressive 9 1/2-length victory at Delaware Park in the "Jock" LaBelle Memorial Stakes May 7.

"Harvey is just a super owner, and this is a real shame," said McLaughlin. "This was a very, very nice horse. He was one of the best 3-year-olds in the country over a mile--we knew that--and we were going to stretch him out to find out far he could go.

"I also feel bad for (trainer) Lynda Knee, who had him for most of his career. She did a great job with the horse and I know she had a special relationship with him."

The LaBelle win earned Egg Head a Beyer Speed Figure of 112, one of the year's highest postings for a 3-year-old at any distance, and also high on the rankings among all ages up to a mile. He made seven career starts, winning four, and earning $145,420.

Egg Head made his first start under McLaughlin's tack in the Riva Ridge Stakes (gr. II) June 11 at Belmont. The race was memorable for featuring an undefeated Lost in the Fog, who was given his stiffest test to date by a game Egg Head who finished just 1 1/4 lengths behind the superstar.

Owners Bring Wrongful Death Claims

by Pete Spanos
Date Posted: October 13, 2005
Last Updated: October 16, 2005

Millionaire Saratoga County among

The owners of rising 3-year-old sprint star Egg Head and millionaire sprinter Saratoga County are among a group of six Thoroughbred owners bringing suit in the alleged wrongful deaths of three racehorses and for severe damage to a fourth, according to a recent report in the Schenectady, N.Y. *Daily Gazette*.

In a civil action filed Sept. 29 in the United States District Court for the Northern District of New York in Albany, plaintiffs are claiming negligence, breach of warranty, and strict products liability against the New Jersey-based Wedgewood Village Pharmacy involving an antibiotic product they claim necessitated the humane killing of the animals in the weeks leading up to the 2005 Saratoga race meet.

In a civil action filed Sept. 29 in the United States District Court for the Northern District of New York in Albany, plaintiffs are claiming negligence, breach of warranty, and strict products liability against the New Jersey-based Wedgewood Village Pharmacy involving an antibiotic product they claim necessitated the humane killing of the animals in the weeks leading up to the 2005 Saratoga race meet.

about July 11."

The cause cites improper design, manufacture, compounding, formulation, mixing and/or labeling, (which) "led to the slow, painful demise of these horses."

Richlyn Farm, a Saratoga Springs, N.Y. corporation, owned the 4-year-old Saratoga County, winner of the $2 million Gulf News Dubai Golden Shaheen (UAE-I) in March. Trained by George Weaver, the son of Valid Expectations was to stand at stud at Vinery in Florida beginning in 2006.

Cathy's Choice, a 3-year-old filly was owned by Catherine and Donald Flanagan of Massachusetts; and Yankee Penny, an undefeated 3-year-old daughter of Quiet American for Weaver, is owned by John Peace.

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  - Equine Directory
- Glossary
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Please Pass the Sugar Cubes

Online News

Concentrated Counterfeit Clenbuterol Having Deadly Effect

by: Erin Ryder, Staff Writer

November 22 2006 Article # 8230

Article Tools

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Veterinarians at Louisiana State University have confirmed that two horses being treated at their veterinary teaching hospital died after ingesting concentrated clenbuterol. Tests on the drug have revealed that the solution contains 70 times the amount of clenbuterol as the FDA-approved formula.

The Louisiana State Veterinarian's office and the FDA are investigating the cases. While veterinarians at the hospital verified that the two horses died after ingesting the drug, they stressed that tests on blood levels of the drug have not yet confirmed that it caused the deaths.

"We don't have confirmation of anything yet--but we did have cases come through here, and two died," said Rebecca McConnico, DVM, PhD, Dipl. ACVIM, who treated the horses when they were admitted to the LSU hospital. She says the horses had clinical signs consistent with colic--they were sweating profusely, anxious, and had high heart rates.

McConnico said the clenbuterol was packaged in a white plastic container with a white label, marked "Clenbuterol HCl, 72.5 micrograms" in black lettering. No brand name or manufacturer was labeled on the bottle.

Steven Barker, PhD, did the drug testing on the sample submitted by the horses' owner. He is the state chemist as well as the director of Analytical Systems Laboratories and the Equine Medication Surveillance Laboratory at LSU.

"They thought perhaps the material in the bottle wasn't clenbuterol, or that it was some toxic material," Barker said. "As it turns out, we tested the material in the bottle and it was clenbuterol--it's just that the concentration that was there was approximately 70 times what it should have been. So these animals received an overdose of clenbuterol, which had severe physiological effects."

Barker said the people who brought the horses and bottle to the hospital stated that they had purchased the bottle in a tack shop at a Texas racetrack. The horses that became ill were stabled at Evangeline Downs in Louisiana, according to another source.

There are currently two legitimate clenbuterol medications for horses available in the United States. The FDA has approved Ventipulmin and Aeropulmin, both manufactured by Boehringer-Ingelheim, for equine use.

Clenbuterol is a bronchodilator, and it is used in horses with respiratory problems to relax smooth muscles the airway, causing the airway to dilate. It also stimulates the activity of the cilia in the trachea, assisting the process of eliminating mucus and microscopic debris. It can be administered orally; with careful dosing, side effects are minimal.

Concentrated Counterfeit Clenbuterol Having Deadly Effect

by: Erin Ryder, Staff Writer

November 22 2006 Article # 8230

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“Just like Ventipulmin but cheaper”

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FDA Warning Letters

Page 3 – Dr. Warren B. Lee, President
Lee Pharmacy, Inc.
October 6, 2003

This same lot was the subject of a Consumer Complaint (No. 15698). FDA collected two previously opened 10mL brown glass vials containing Methylprednisolone Acetate 40mg/ml P.F. from the complainant's clinic on November 25, 2002. Upon examination of the product, in the condition as received, mold was recovered from one of the two vials (sample number 118711). We acknowledge that you did recall all preservative free injectables compounded in year 2002, which included this lot.

FDA also collected a physical sample of Triamcinolone Acetonide 40mg/ml P.F. from batch 20062002:28 (sample number 169598). The 3,000-mL batch was compounded on June 20,2002, and had a "Use By" date of 06-03. The sample was tested for potency and was found to be sub-potent with aliquots from two sub-samples confirmed at 67.8% and 79.8% of label claim for potency.

The lot of Methylprednisolone Acetate Injection, which was recalled by your firm, violated Section 501(a)(1) of the Federal Food, Drug and Cosmetic Act (the Act), in that it consisted in whole or in part of a filthy, putrid, or decomposed substance. The lot of Triamcinolone Acetonide Injection, which has expired, violated Section 501(c) as labeled, or 501(b) if it is a suspension product (as the label and formulation imply), in that the strength differs from that which it purports or is represented to possess.

FDA Warning Letters

Page 4 - Mr. John R. Rains, R. Ph., CEO
Plum Creek Pharmaceuticals, Inc.
October 7, 2003

ANIMAL DRUGS:

Your firm also compounds veterinary prescription drug products, compounded with the use of bulk active pharmaceutical ingredients (APIs). The current inspection documented the compounding of the following drugs:

- Methyltestosterone 50mg tablets – this drug was compounded and shipped to a veterinary clinic. A total of 9,856 tablets were compounded in 2 batches, one in November 2002, and a second in January 2003, and;

- Yohimbine hydrochloride 10mg/ml injection – this drug was compounded and shipped to veterinary clinics in 13 states in the 90 days prior to the inspection date. A total of 8 production batches accounted for production of 32,220 ml of product.

The veterinary drugs compounded and distributed by your firm are new animal drugs within the meaning of Section 201(v) of the Act. These drugs are adulterated under Section 501(a)(5) of the Act because they are unsafe within the meaning of Section 512 of the Act. Under Section 512, a new animal drug is deemed to be unsafe unless an approved New Animal Drug Application (NADA) is in effect for the specific product in question. None of the animal drugs compounded and distributed by your firm are the subject of an approved NADA.

Select Text Tool

Drug Name	Trade and Other Name	Drug Classification	Forms Available
Acepromazine Maleate	ProMACE®	Antiemetic, Tranqulizer, Phenothiazine Tranqulizer	powder, suspension, paste
Acetazolamide	Diamox®	Diuretic	powder, suspension
Acetylcysteine	Mucomyst®	Mucolytic, Antidote	capsules, suspension, oral solution, injection, opthalmic
ACTH	Acthar Gel®	Peptide Hormone	injection
Adenosine Monophosphate	AMP	Organic Compound	injection
Adenosine Triphosphate	ATP	Organic Compound	injection
Albuterol	Ventolin®, Proventil®	Beta-antagonist, Bronchiodilator	powder, syrup, oral solution
Alluminum Hydroxide	Amphogel®, Basalgel®	Antacid	capsules, suspension, paste
Amikacin	Amiglyde-V®	Antibacterial	suspension, oral solution, injection, PLO
Aminocaproic Acid	Amicar®	Antifibrinolytic	suspension, oral solution
Aminophylline	Aminophylline	Bronchodilator	capsules, suspension, topical ointment, PLO
Amitraz	Mitaban®	Antiparasitic	topical solution
Amitriptyline	Elavil®	Behavior Modifier, Tricyclic Antidepressant	capsules, suspension, oral solution, paste, injection, PLO
Amlodipine Besylate	Norvasc®	Calcium Channel Blocker	capsules, suspension,
Ammonium Chloride	Uroeze®	Acidifier	powder, capsules, suspension, oral solution, injection
Ammonium Sulfate	Nervine®	Acidifier	oral solution, injection
Amoxicillin + Clavulanate Potassium	Clavamox®	Antibacterial	suspension
Amphotercin B	ABELCET®	Antifungal	suspension, oral solution
Ampicillin Trihydrate	Polyflex®	Antibacterial	powder, capsules, suspension
Anti Bacterial Itch Cream	Panalog®	Antibacterial, Antifungal	topical cream, ointment and lotion
Anti-diarrheal	Diathol®	Antidiarrheal	injection
Apomorphine	Apomorphine TT	Emetic	powder, capsules, suspension, oral solution, injection, opthalmic
Ascorbic Acid	Vitamin C	Vitamin	suspension, injection, topical cream
Aspirin	Aspirin	Analgesic, NSAID	powder, capsules, suspention, paste, injection, PLO
Atenolol	Tenormin®	Beta-blocker	capsules, suspension, PLO
Atropine	Atropine	Anticholinergic	capsules, suspension, oral solution, injection,opthalmic
Azathioprine	Imuran®	Immunosuppresive	capsules, suspension
Azithromycin	Zithromax®	Antibacterial	powder, capsules, suspension, paste, suppository
Benazepril	Fortekor®, Lotensin®	Vasodilator, ACE inhibitor	capsules, suspension
Betamethasone Sodium Acetate	Celestone®	Corticosteroid	injection
Bethanecol	Urecholine®	Cholinergic	powder, capsules, suspension, injection
Bismuth Subsalicylate	Pepto Bismol®	Antidiarrheal	powder, capsules, suspension, paste

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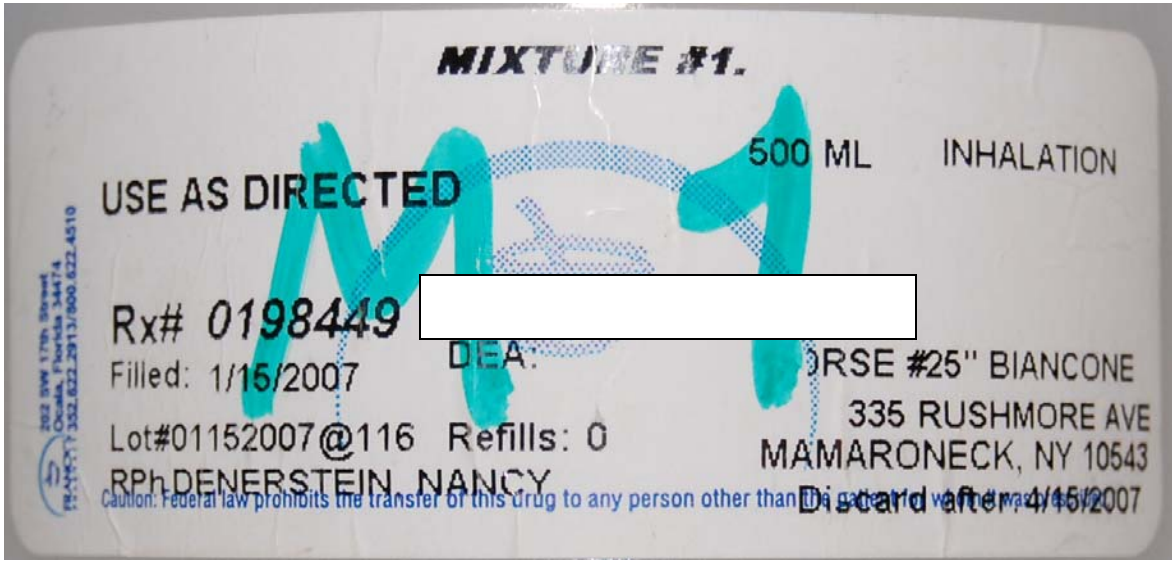
- **Hipp-Iron** *(Ferric Succrose)* 20mg/ml 50ml.....**$45.00**
- **Homeopathic Nervous Injection** 100ml.....**$75.00** ☑**Pharmacy Exclusive IT WORKS!**
- **Guafenisin** 50mg/ml 1000ml.....**$50.00** *-Purchase 12 or more $40*
- **Methocarbomol** 5gm/scoop *-100 scoops apple flavored*.....**$130.00**
- **Methocarbomol**100mg/ml *-100ml injection*.....**$35.00**

All homeopathic paste and injections

Serenity Calmer Paste $10 Each
Nervous Horse Injection 100ml. $75

American Association of Equine Practitioner 2009

Illegal Veterinary Compounding



The compounding pharmacy advised that Mixture #1 was proprietary formulation.

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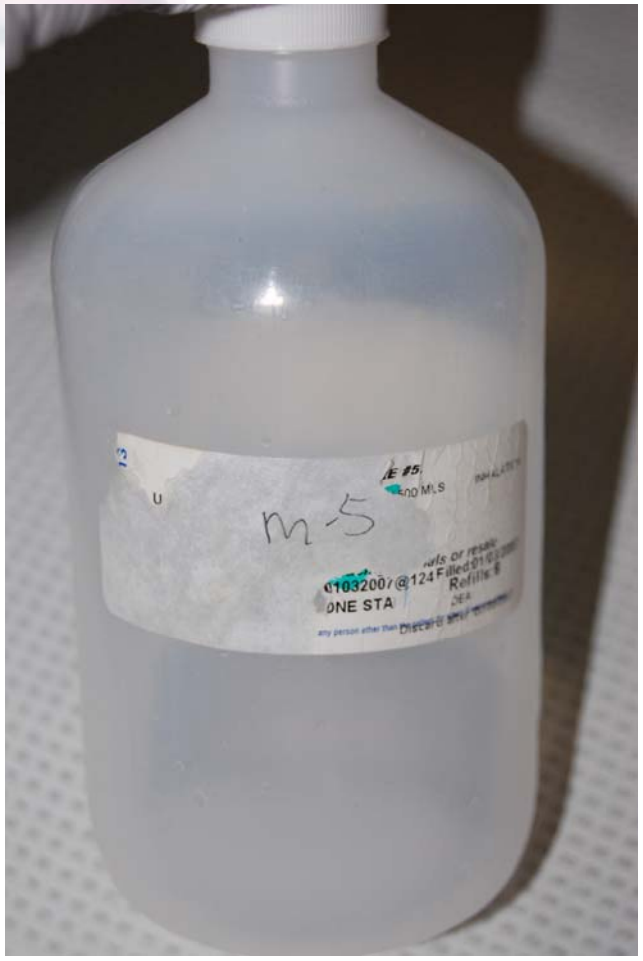
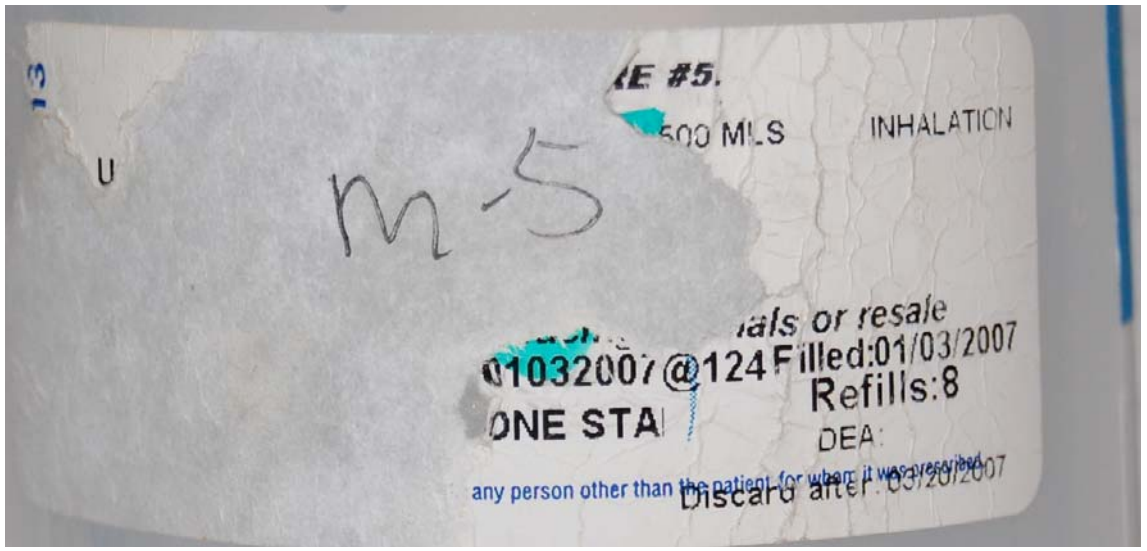
Illegal Veterinary Compounding





The compounding pharmacy advised that Mixture #5 was the same as Mixture #1 with an additional active ingredient. (**Salmeterol**)

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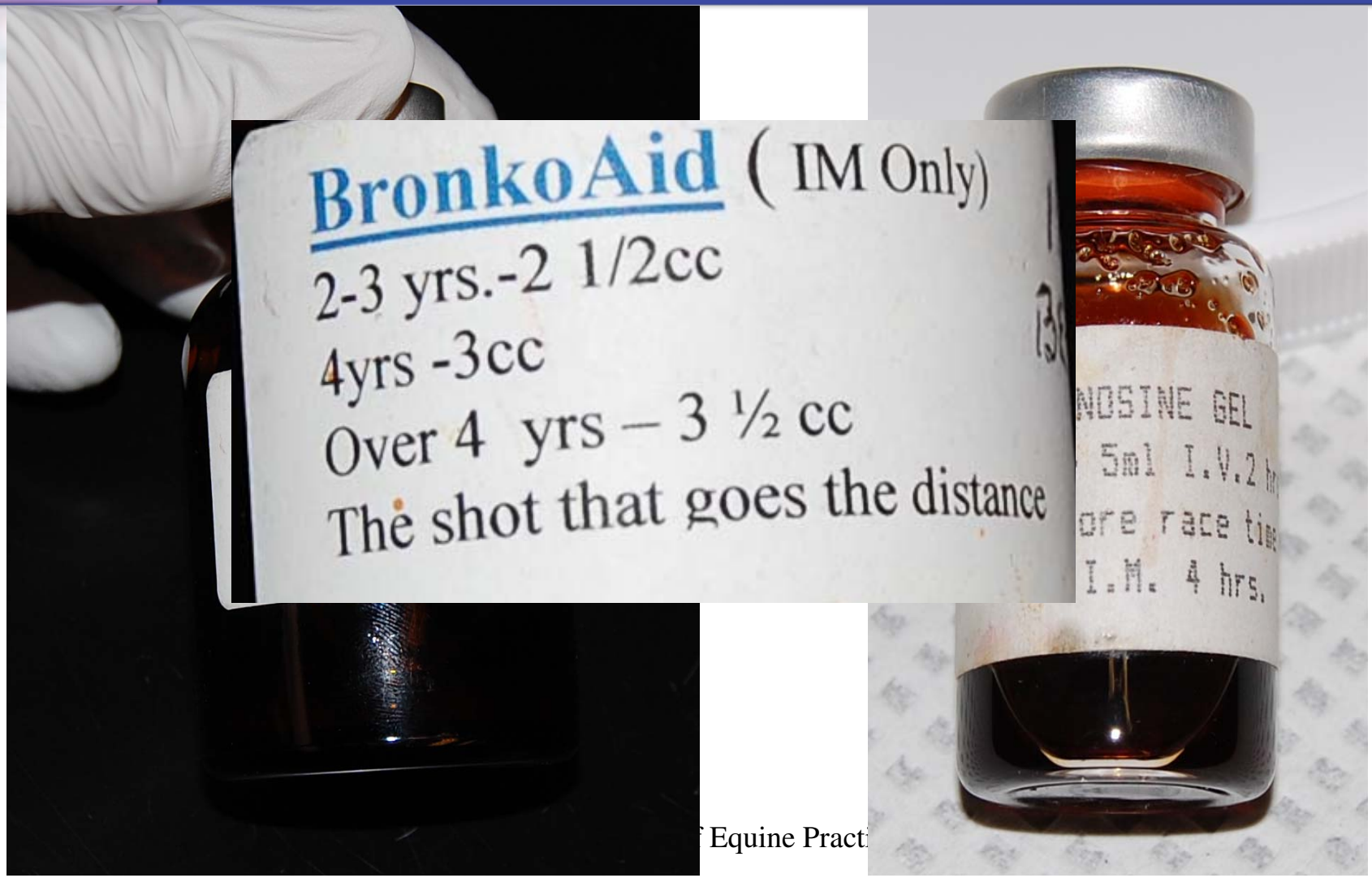
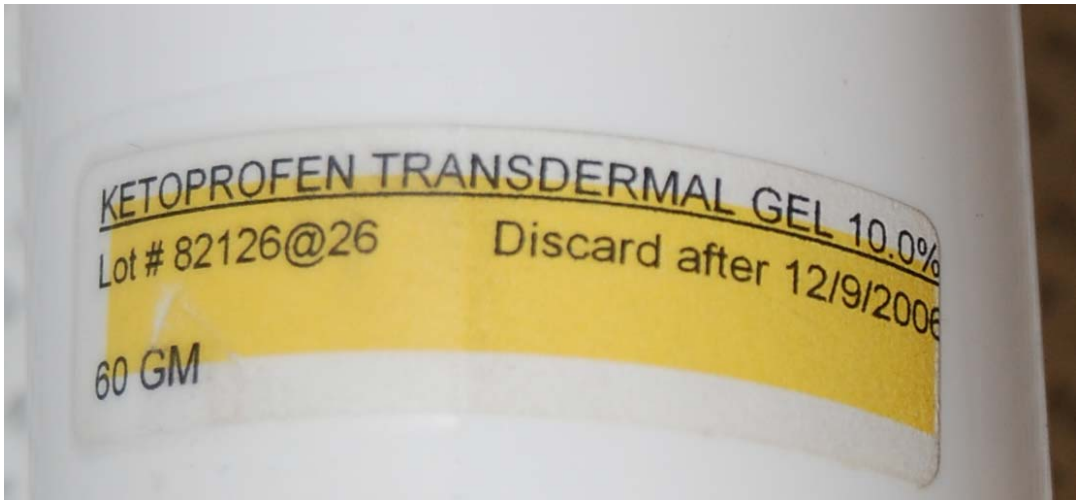
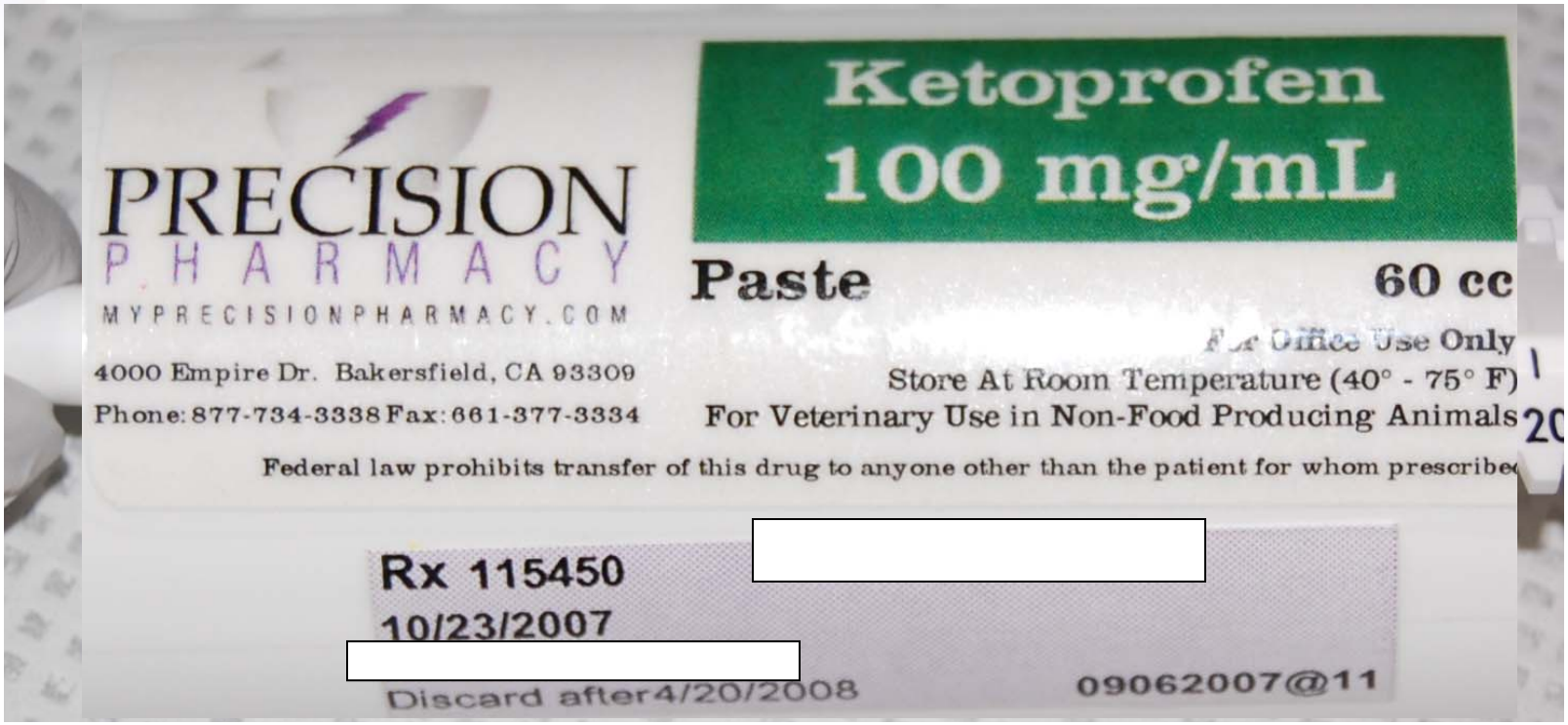
Unknown Compounds



Ketoprofen Gel



Ketoprofen Paste



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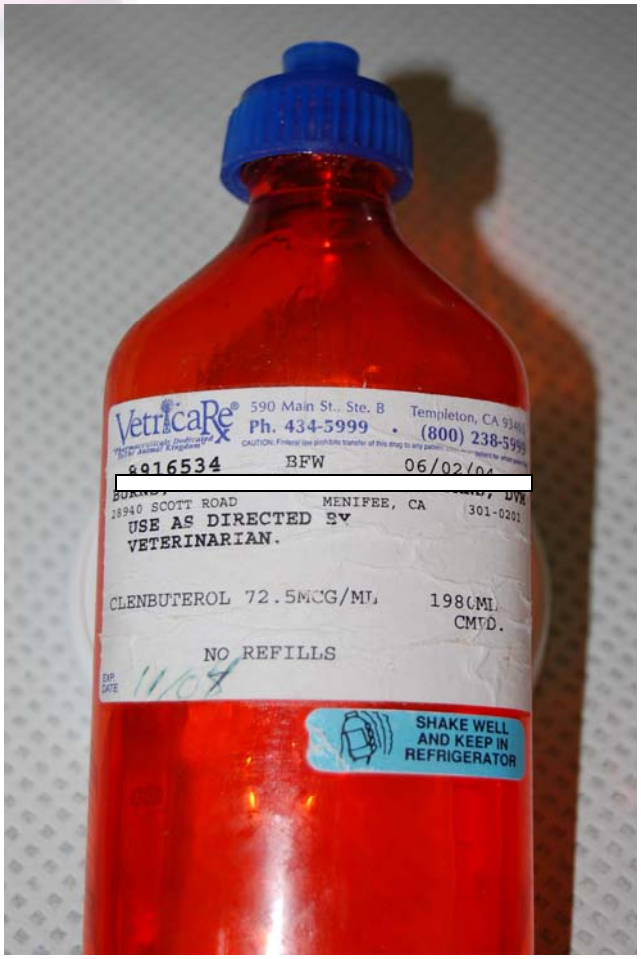
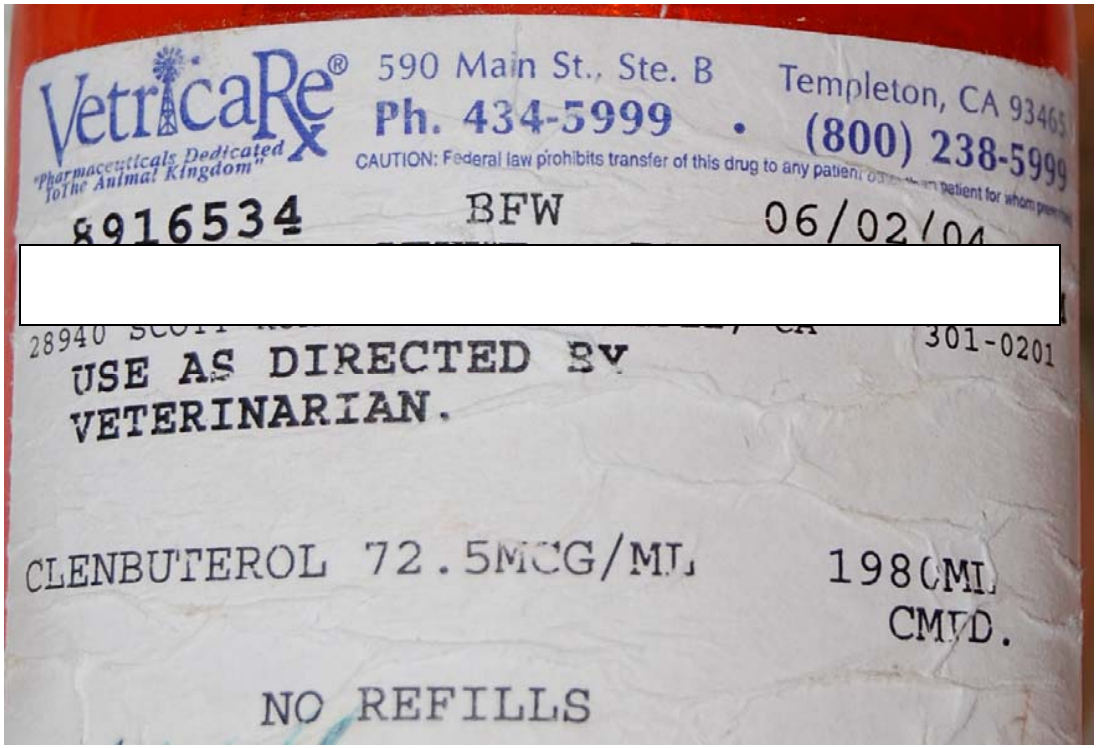
Clenbuterol Solution





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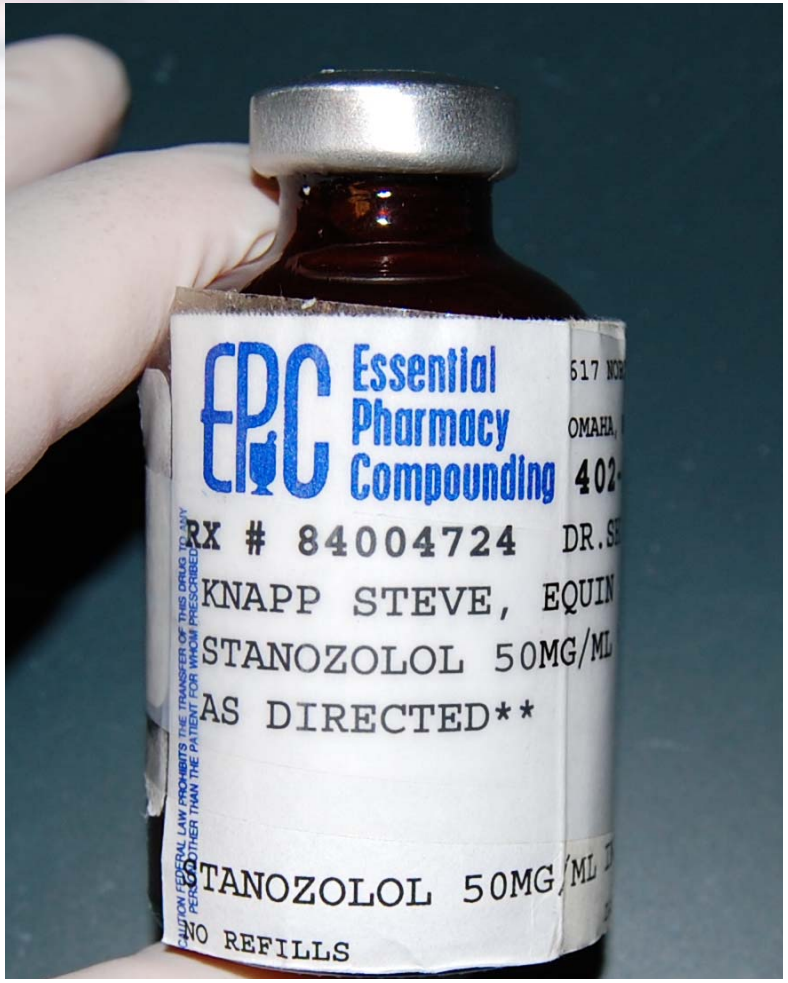
Anabolic Steroids



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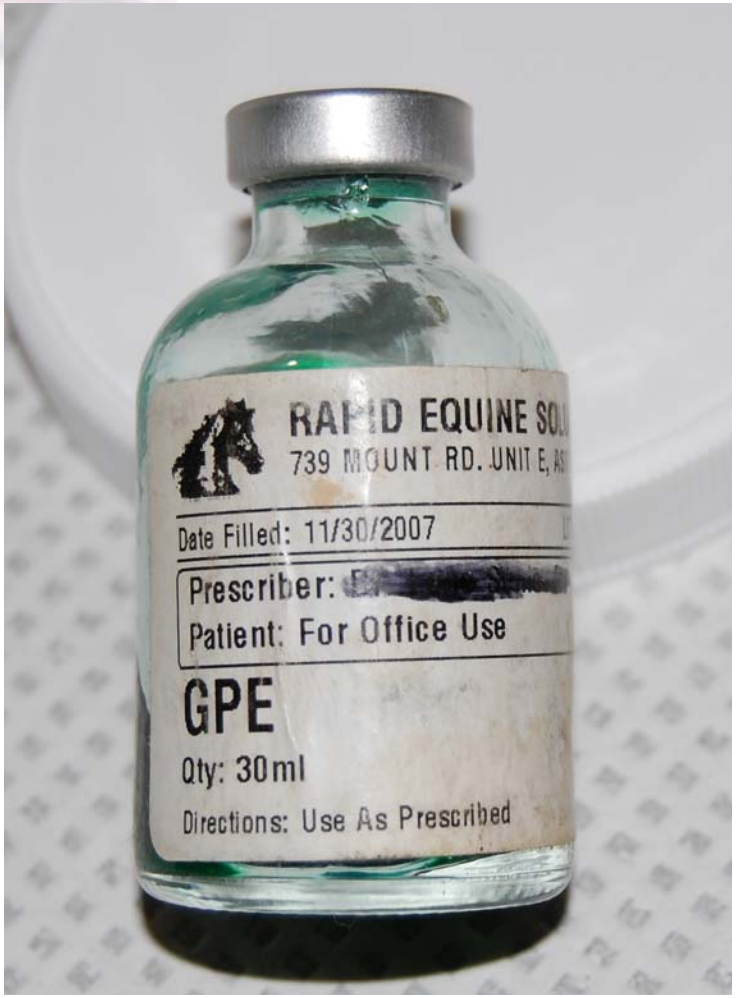
Glycine-Proline-Glutamate



GPE is the N-terminal tripeptide of insulin-like growth factor-1 and has been shown to be neuroprotective following ischemia-induced brain injury.

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Flunixin Injection

Flunixin analysis determined concentration was only 68% of the label claimed potency!

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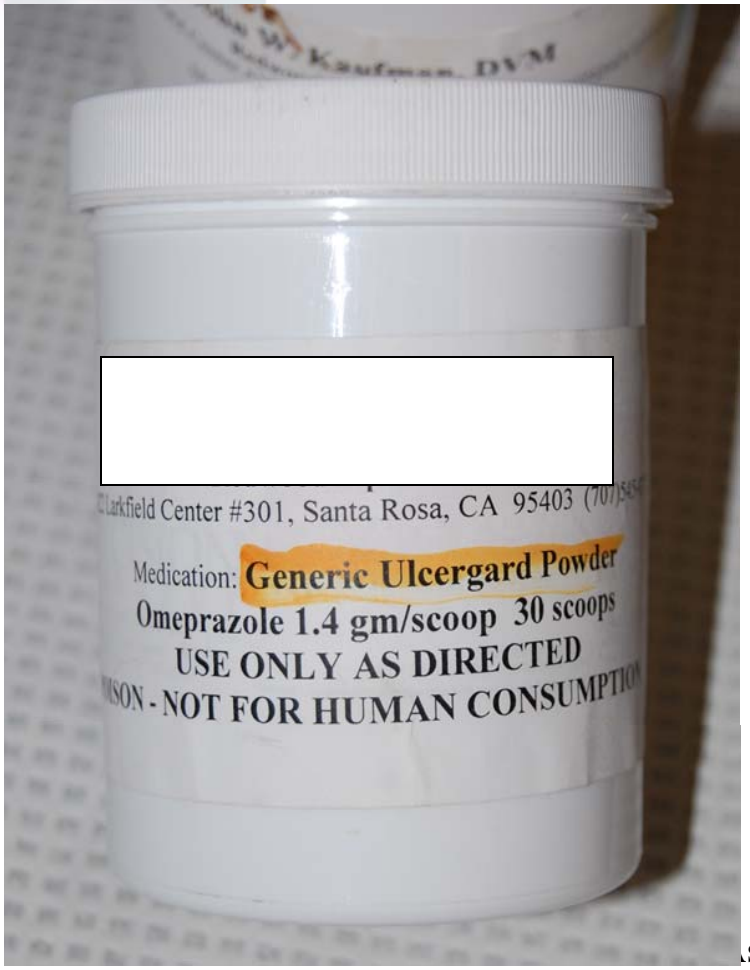
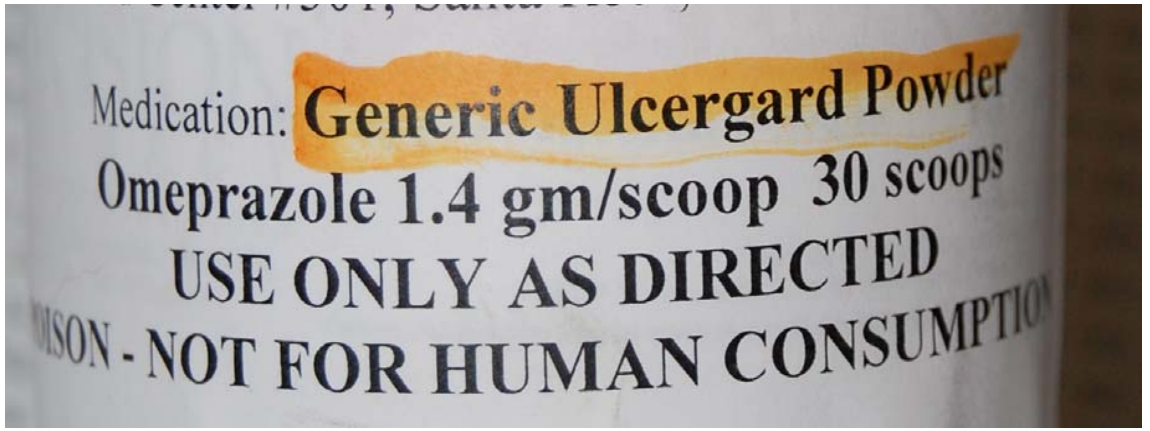
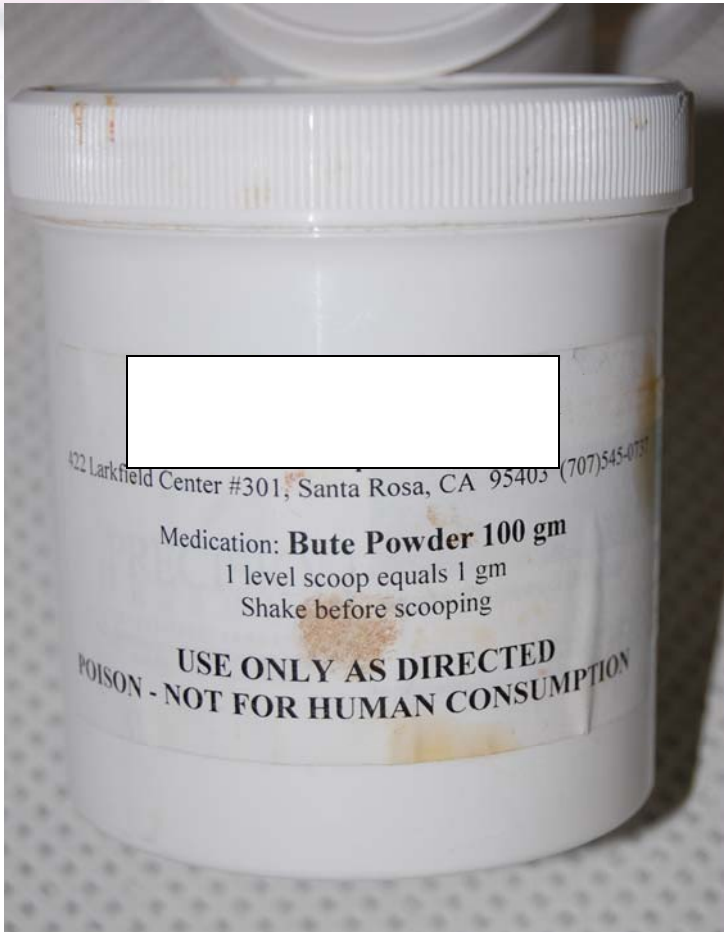
Omeprazole Powder

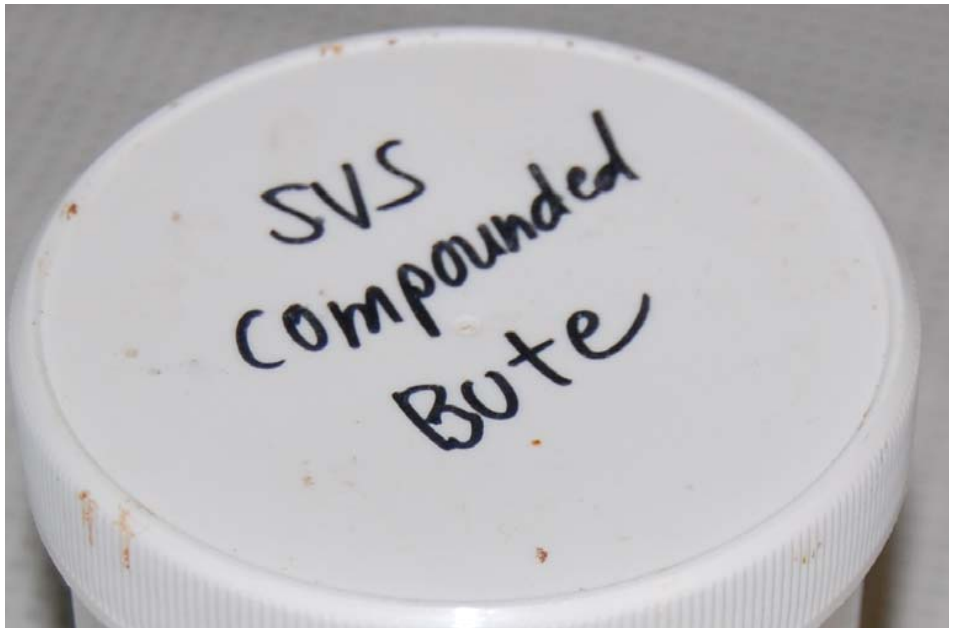




Omeprazole powder analysis determined concentration was only 78% of the label claimed potency!

Phenylbutazone Powder





Phenylbutazone powder analysis determined concentration was only 72% of the label claimed potency!

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Illegal Veterinary Compounding

Modafinil is used treatment of narcolepsy . Modafinil has received some publicity in the past when several athletes were discovered allegedly using it as a performance-enhancing doping agent. Modafinil was added to the World Anti-Doping Agency "Prohibited List" in 2004 as a prohibited stimulant.

American Association of Equine Practitioner 2009

Industry Concerns:

- Major source of new medications for veterinary medicine are diminishing
- Drug discovery is very expensive
- Most veterinary drugs have come via parent company human research initiatives
- More pharmaceutical companies have consolidated and their animal health divisions could be sold or eliminated if they are profitable

Recommendations:

- Use FDA approved products when available
- Use a compounding pharmacist that follows FDA Guidelines for Good Compounding Practices and has product liability insurance
- Use compounded products only for individual animals

Recommendations:

- Avoid off label use of devices as drugs
- Do not tell a your clients that a device or a compounded drug is a “generic” form of an approved FDA product!