Legal and Ethical Veterinary Compounding

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

**Drug Detection**
- Determination, Identification, Confirmation

**Pharmacokinetics**
- $T_{1/2}$, AUC, CI, Metabolite ID

**Proteomics**
- Erythropoietin, Growth Hormone, Cobratoxin

Clenbuterol m/z 240
Horse Industry Integrity

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

American Association of Equine Practitioner 2009
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 $\pm 10\%$ 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
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

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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

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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
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

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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*

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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.
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.
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
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:

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<th>Compounder (100 mg/mL)</th>
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</table>
Amikacin Potency:

![Graph showing Amikacin Concentration (mg/mL) for Amiglyde-V® and Compounder (250 mg/mL) across different pharmacies.](image-url)
Boldenone Potency:

- **Equipoise® (50 mg/ml)**
- **Compounder (50 mg/ml)**
- **Compounder (25 mg/ml)**
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:

![Graph showing Amikacin purity across different pharmacies. The x-axis represents the pharmacies labeled as 2, A, B, C, D, E, F, and G. The y-axis represents the percentage of total impurities ranging from 0.0 to 2.5. The graph compares Amiglyde-V® (250 mg/ml) in purple and the Compounder (250 mg/ml) in teal. ]
Boldenone Purity:

![Graph showing the purity of Boldenone in different pharmacies. The graph compares Equipoise® (50 mg/mL), Compounder (50 mg/mL), and Compounder (25 mg/mL). The y-axis represents % Total Impurities, ranging from 0 to 5. The x-axis represents the pharmacies: 1, C, E, F, L, G. The Graph shows a significant difference in purity levels across the pharmacies.]
Medical Therapy for Equine Joint Disease: Understanding your Choices?
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)**

American Association of Equine Practitioner 2009
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)
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
Common products compounded for equine joint disease

- betamethasone suspension
- acetyl-d-glucosamine injection
- HA injection
- “cocktail injections” containing glucosamine, HA and chondroitin
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.

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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.
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
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
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

American Association of Equine Practitioner 2009
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 founder. 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.

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Owners Bring Wrongful Death Claims

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

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 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 Dubal Golden Shaheen (UAE-T) 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.
Concentrated Counterfeit Clenbuterol Having Deadly Effect

by: Erin Ryder, Staff Writer

November 22 2006 Article # 8230

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 McConico, 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.

McConico said the clenbuterol was packaged in a white plastic container with a white label, marked "Clenbuterol HCI, 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 Ventulmin 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.
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McConnico said the clenbuterol was packaged in a white plastic container with a red lid and was not clearly labeled as a banned substance.
McConico 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.

“Just like Ventipulmin but cheaper”

"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."

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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.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Trade and Other Name</th>
<th>Drug Classification</th>
<th>Forms Available</th>
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<tr>
<td>Acepromazine Maleate</td>
<td>Promace®</td>
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<td>Uroez®</td>
<td>Acidifier</td>
<td>powder, capsules, suspension</td>
</tr>
<tr>
<td>Ammonium Sulfate</td>
<td>Nervine®</td>
<td>Acidifier</td>
<td>oral solution, injection</td>
</tr>
<tr>
<td>Amoxicillin + Clavulanate Potassium</td>
<td>Clavamox®</td>
<td>Antibacterial</td>
<td>suspension</td>
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<tr>
<td>Ampicillen B</td>
<td>ABELCET®</td>
<td>Antifungal</td>
<td>suspension, oral solution</td>
</tr>
<tr>
<td>Ampicillin Trihydrate</td>
<td>Poliflex®</td>
<td>Antibacterial</td>
<td>powder, capsules, suspension</td>
</tr>
<tr>
<td>Anti Bacterial Itch Cream</td>
<td>Panalog®</td>
<td>Antibacterial, Antifungal</td>
<td>topical cream, ointment</td>
</tr>
<tr>
<td>Anti-diarrheal</td>
<td>Diatholi®</td>
<td>Antidiarrheal</td>
<td>injection</td>
</tr>
<tr>
<td>Apomorphine</td>
<td>Apomorphine TT</td>
<td>Emetic</td>
<td>powder, capsules, suspension</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>Vitamin C</td>
<td>Vitamin</td>
<td>suspension, injection, topical</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Aspirin</td>
<td>Analgesic, NSAID</td>
<td>powder, capsules, suspension</td>
</tr>
<tr>
<td>Atenolol</td>
<td>Tenormin®</td>
<td>Beta-blocker</td>
<td>capsules, suspension, PLO</td>
</tr>
<tr>
<td>Atropine</td>
<td>Atropine</td>
<td>Anticholinergic</td>
<td>capsules, suspension, oral</td>
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<tr>
<td>Azathioprine</td>
<td>Imuran®</td>
<td>Immunosuppressive</td>
<td>capsules, suspension</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>Zithromax®</td>
<td>Antibacterial</td>
<td>powder, capsules, suspension</td>
</tr>
<tr>
<td>Benazepril</td>
<td>Fortekor®, Lotensin®</td>
<td>Vasodilator, ACE inhibitor</td>
<td>capsules, suspension</td>
</tr>
<tr>
<td>Betamethasone Sodium Acetate</td>
<td>Celestone®</td>
<td>Corticosteroid</td>
<td>injection</td>
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<tr>
<td>Bethanecol</td>
<td>Urecholine®</td>
<td>Cholinergic</td>
<td>powder, capsules, suspension</td>
</tr>
<tr>
<td>Bismuth Salicylate</td>
<td>Pepto Bismol®</td>
<td>Antidiarrheal</td>
<td>powder, capsules, suspension</td>
</tr>
</tbody>
</table>

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ESSENTIAL PHARMACY COMPOUNDING
A division of Kohll’s Pharmacy and Homecare, Omaha Nebraska
1-888-733-0300   www.kohlls.com

Order Today!
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JUNE 2008 SPECIALS

Hard to Find Compounds
- Toltrazuril Paste (Your Custom Dosage).................................$5.50/gm (EPM)
- Hipp-Iron (Ferric Sucrose) 20mg/ml 50ml.................................$45.00
- Homeopathic Nervous Injection 100ml.................................$75.00 ☑Pharmacy Exclusive IT WORKS!
- Guafensin 50mg/ml 1000ml..................................................$50.00 -Purchase 12 or more $40
- Methocarbamol 5gm/scoop -100 scoops apple flavored..................$130.00
- Methocarbamol 100mg/ml -100ml injection.................................$35.00

All homeopathic paste and injections
- Serenity Calmer Paste $10 Each
- Nervous Horse Injection 100ml $75

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Illegal Veterinary Compounding

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

BronkoAid (IM Only)

2-3 yrs. - 2 1/2 cc
4 yrs - 3 cc
Over 4 yrs - 3 1/2 cc
The shot that goes the distance

American Association of Equine Practitioners
Ketoprofen Gel

American Association of Equine Practitioner 2009
Ketoprofen Paste

American Association of Equine Practitioner 2009
Clenbuterol Solution

American Association of Equine Practitioner 2009
Anabolic Steroids

American Association of Equine Practitioner 2009
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.

American Association of Equine Practitioner 2009
Flunixin Injection

Flunixin analysis determined concentration was only 68% of the label claimed potency!
Omeprazole powder analysis determined concentration was only 78% of the label claimed potency!
Phenylbutazone powder analysis determined concentration was only 72% of the label claimed potency!

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Modafinil is used in the 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.
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

American Association of Equine Practitioner 2009
Recommendations:

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