

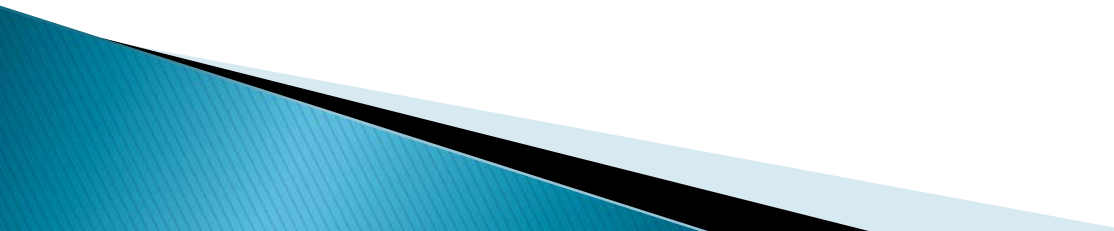
# Compounded Substances

Dr. Dionne Benson

Dr. Lynn Hovda


Dr. Scott Stanley

# Compounded Substances Basics

- ▶ Compounding is best described as combining, mixing, or altering the ingredients of an FDA approved drug by a licensed veterinarian or pharmacist to meet the specific needs of an individual animal patient
- 

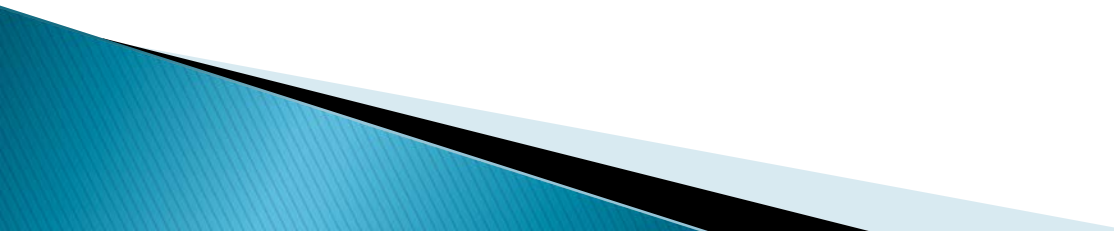
# Compounded Substances

## History of Regulation

- ▶ 1938 – Federal Food, Drug, and Cosmetic Act
  - ▶ 1953 – Veterinary division of Federal Drug Administration (FDA)
  - ▶ 1984 – Center for Veterinary Medicine Drug
  - ▶ 1994 – Animal Medicinal Drug Use Clarification Acts (AMDUCA)
  - ▶ 2016 – FDA CVM regulates pharmaceuticals, including compounded medications, used by veterinarians in their practice.
- 

# Compounded Substances

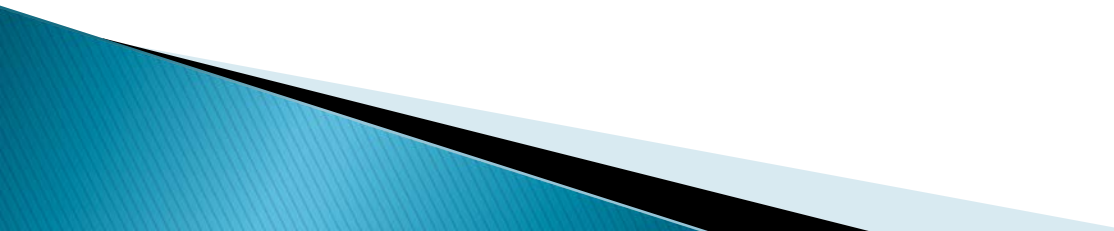
## Why Regulate?

- ▶ NOT FDA approved medications
  - ▶ May not work effectively in the horse
  - ▶ May be more or less potent
  - ▶ May be misbranded
  - ▶ May be contaminated
  - ▶ May be adulterated
- 




# Compounded Substances

## Current Regulations

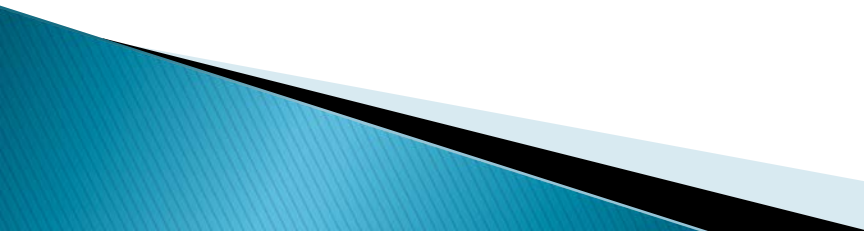
- ▶ Specific animal patient
  - ▶ Appropriately labeled
  - ▶ Made from FDA approved medications
  - ▶ Cannot be made from bulk substances
    - Raw ingredients used to make FDA products
  - ▶ Cannot be made in large amounts and sold/carried by veterinarians for resale
  - ▶ FDA does acknowledge need for large amounts under limited circumstances
- 

# Available Pharmaceuticals

- ▶ FDA–Approved “Pioneer” or “Legend” Drugs
    - Specific for use in the horse
    - Use in other animals
    - Use in human beings
  - ▶ Generic Drugs
  - ▶ Compounded Drugs
- 

# “Pioneer” or “Legend” Pharmaceuticals

## **FDA approval process**

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

# Compounded Substances

## FDA Approved Medication

- ▶ Significant research
- ▶ Safety trials
- ▶ Efficacy trials
- ▶ Stability tests
- ▶ Requirements for consistent concentration of medication

## Compounded Substances

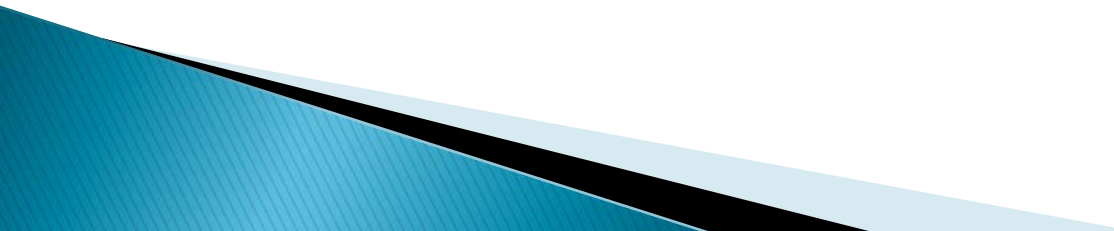
- ▶ No research
- ▶ No safety, efficacy, stability requirements
- ▶ No guarantee of consistent medication concentrations
- ▶ No purity requirements
- ▶ Are not the same as generic medications

# Compounded Substances

- ▶ Veterinarian assumes all liability for damages due to use of compounded medication
- ▶ Veterinarian cannot profit from use of compounded medication
- ▶ Compounded medications include mixtures of FDA approved medications, flavorings



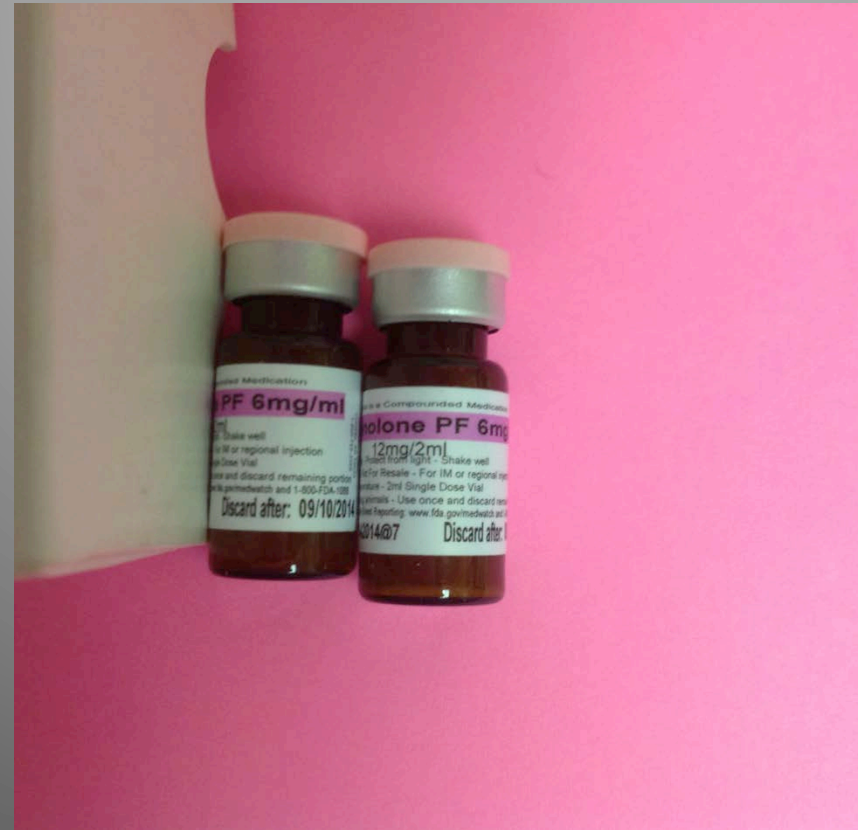
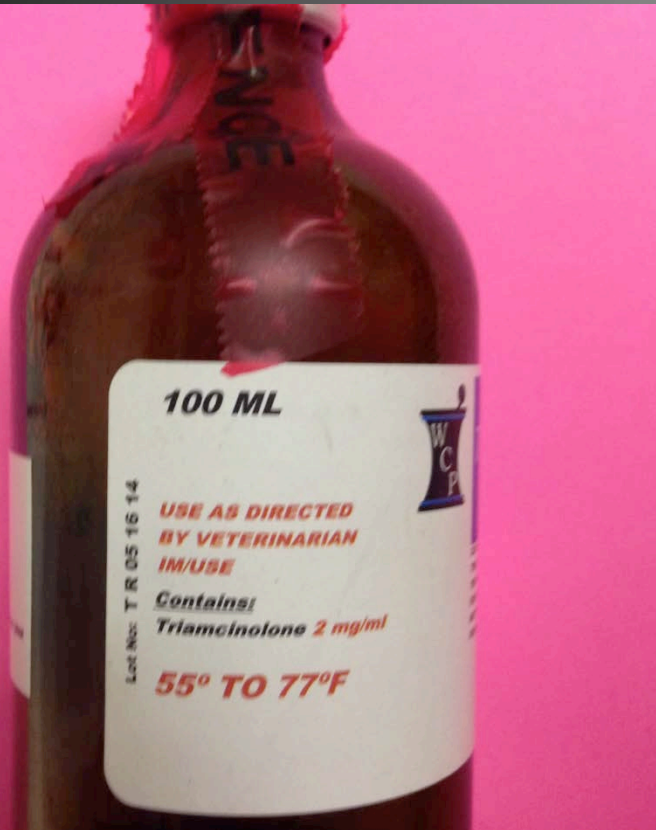
# Compounded Substances

- ▶ 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.
  - ▶ When this occurs, the approved product must be used to make the compounded new dose form.
- 

# Compounding Issues

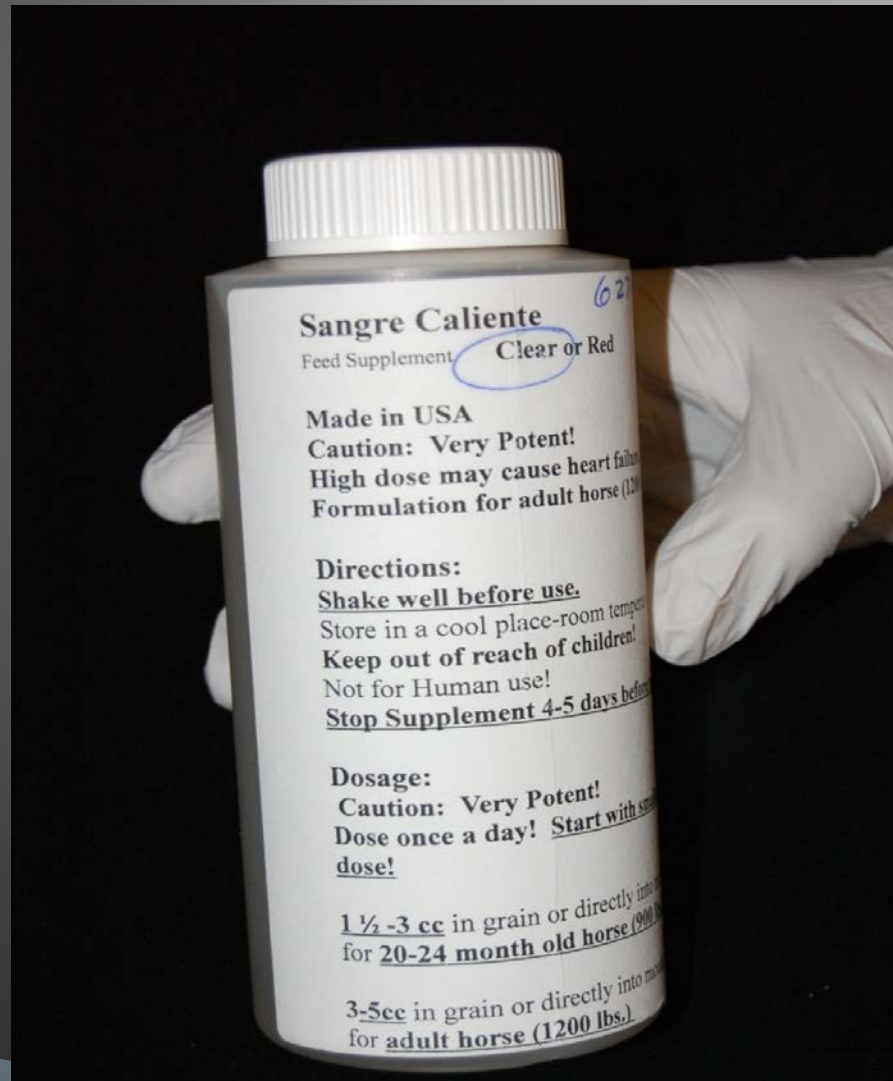


# Triamcinolone...or not

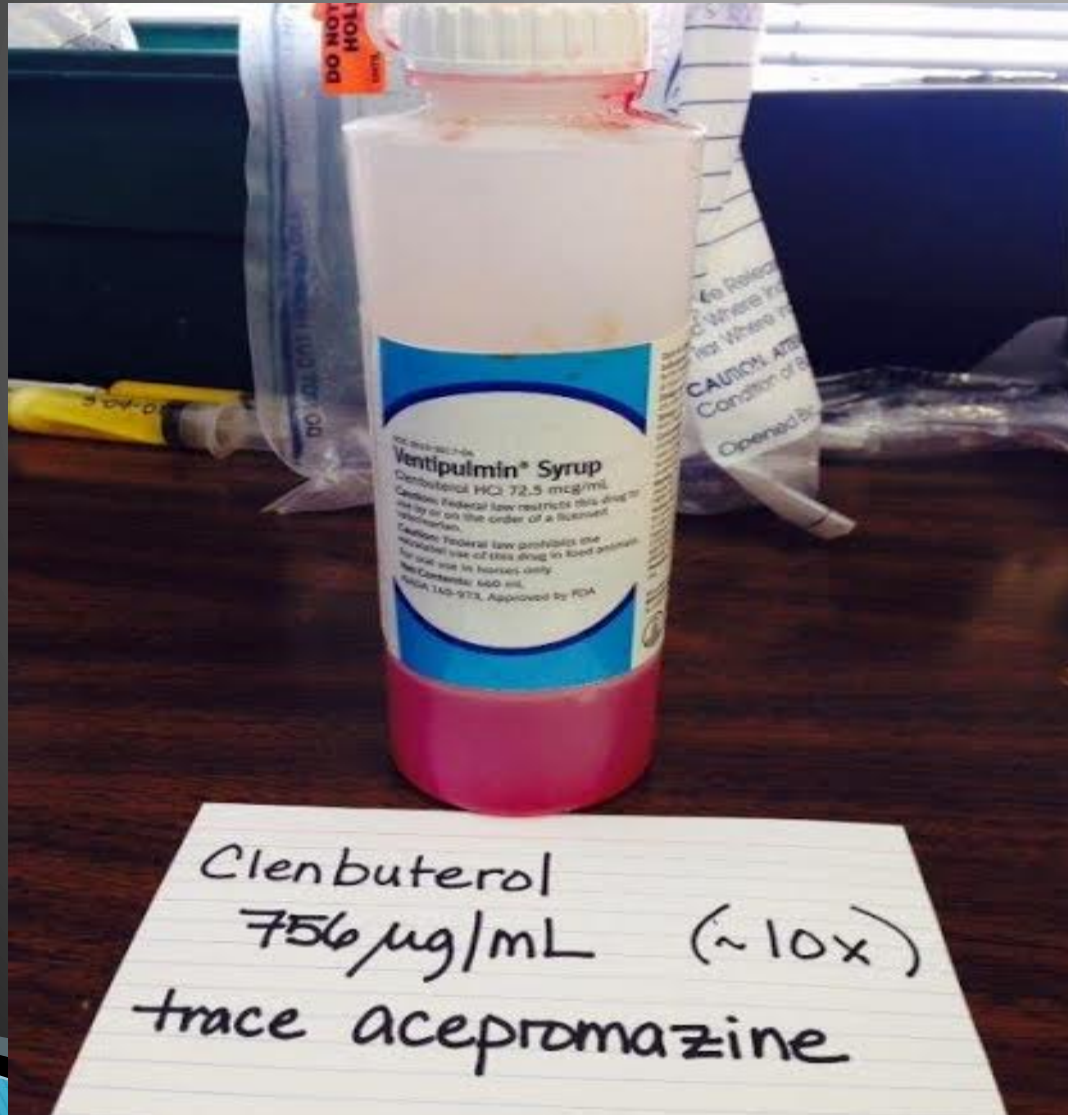




# Sangre Caliente – Clear or Red?



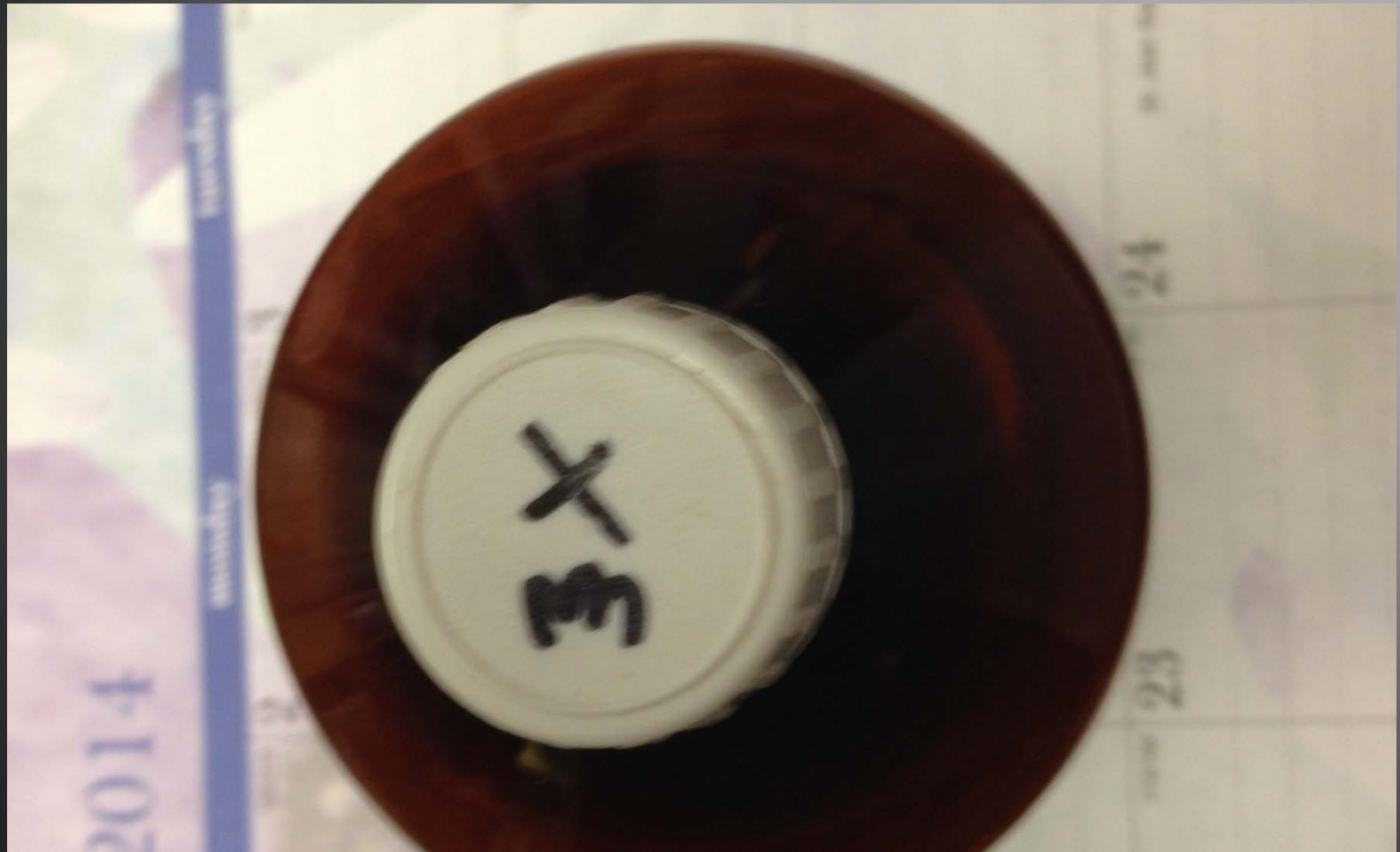
# Clenbuterol 10X



# Plain Brown Bottle?



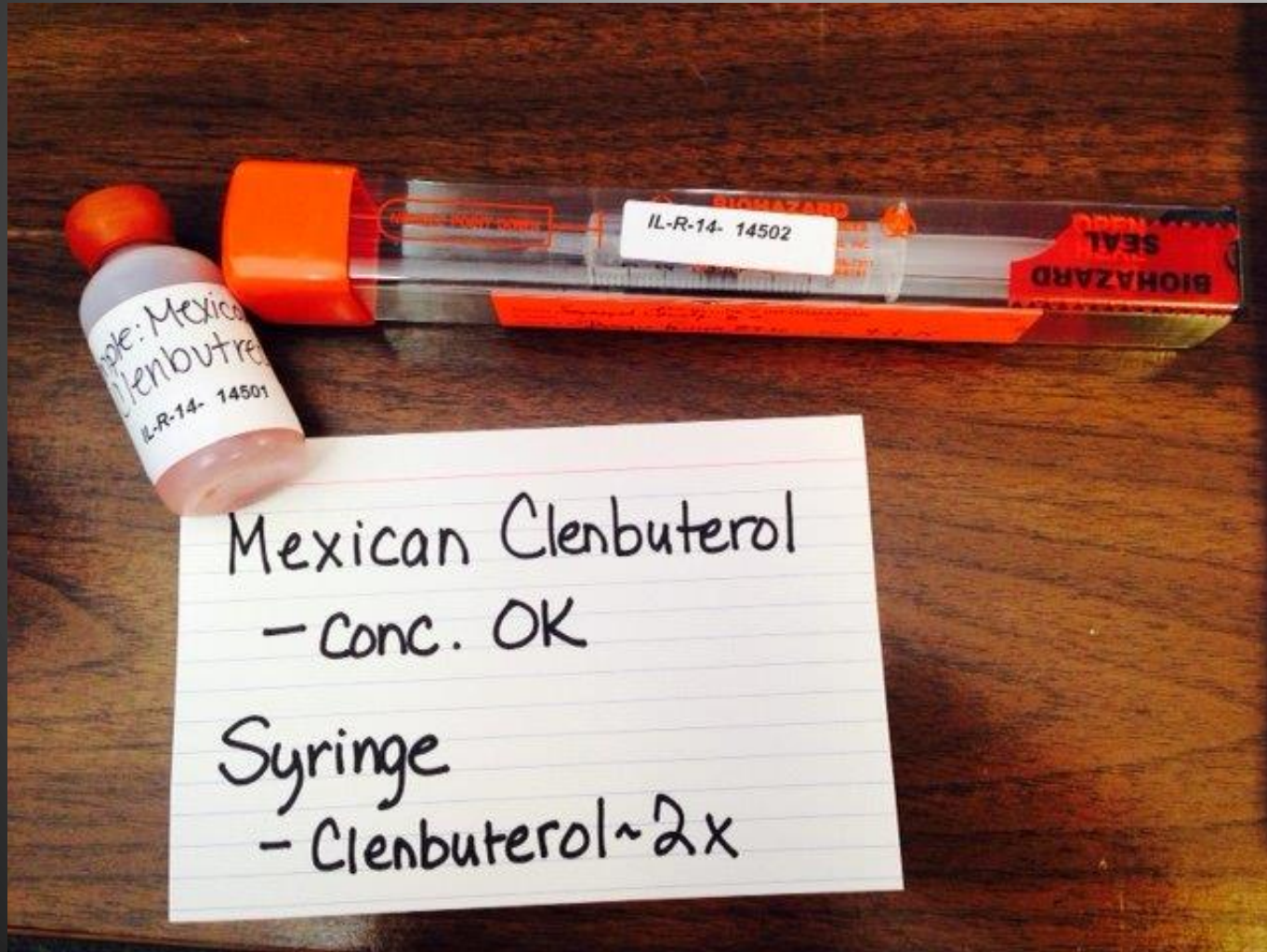
# Clenbuterol



- ▶ Not 2x, not 3x
- ▶ But 1.5 x



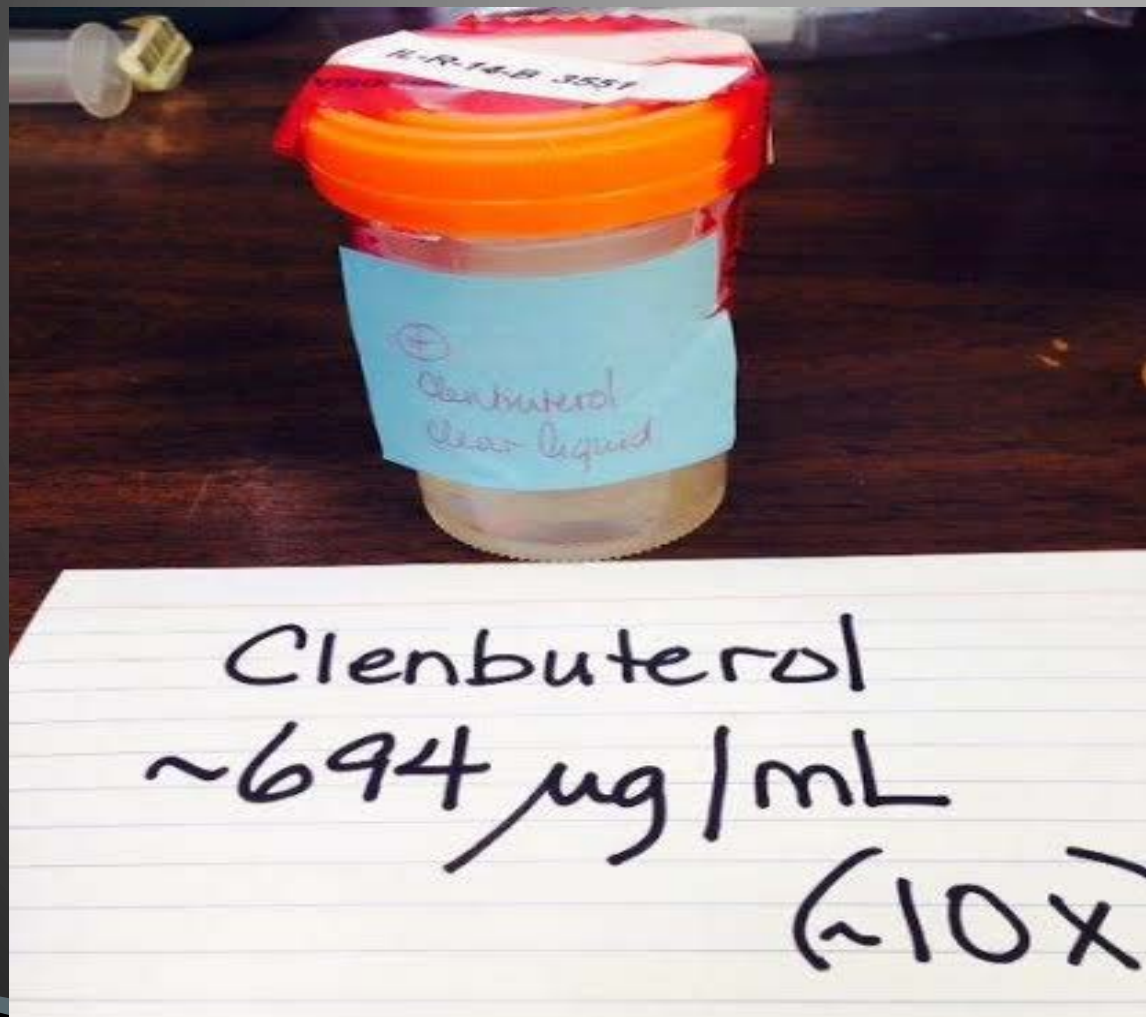
# More Clenbuterol





Clenbuterol  
33  $\mu\text{g}/\text{mL}$   
29  $\mu\text{g}/\text{mL}$   
70.5  $\mu\text{g}/\text{mL}$

# Rocket Fuel or High Test





# Contamination / Misbranded



- ▶ Marketed as Baycox (Toltrazuril/Pyrimethamine Oral Paste)
- ▶ Sold to a trainer
- ▶ 4 positives for levamisole from the same veterinarian





# Legal Compounding versus Illegal Compounding



# Legal versus Illegal Compounding

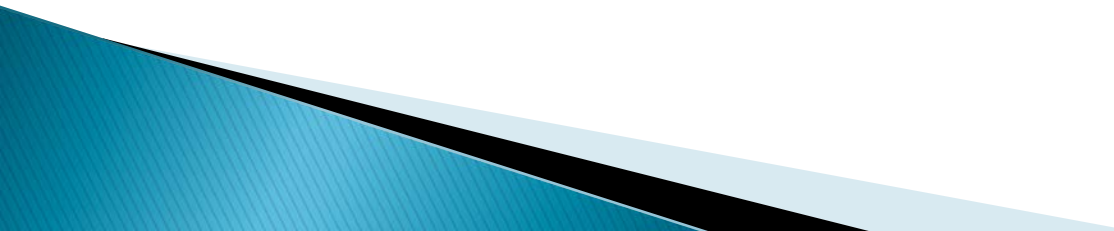
## Legal Compounding

- ▶ Must be done for a specific horse based upon a valid client/patient relationship **and** a specific diagnosis
- ▶ Must be done from legend drugs
- ▶ Must be labeled appropriately
- ▶ Even when done appropriately, this does not mean that it is an FDA approved medication

## Illegal Compounding

- ▶ Uses bulk drugs
- ▶ Bulk manufacturing
- ▶ Inappropriate labeling
- ▶ Not based on a diagnosis
- ▶ No valid patient/client relationship

# Legal Compounding

- ▶ Mixing 2 injectable drugs for a specific horse
    - Corticosteroids and hyaluronic acid for intra-articular injections
    - Butorphanol and detomidine for sedation/pain relief
  - ▶ Crushing tablets to create an oral suspension
    - Methocarbamol tablets mixed with karo syrup
  - ▶ Adding flavoring to a commercially available medication
    - Apple flavored phenylbutazone
  - ▶ Mixing several ointments together
- 





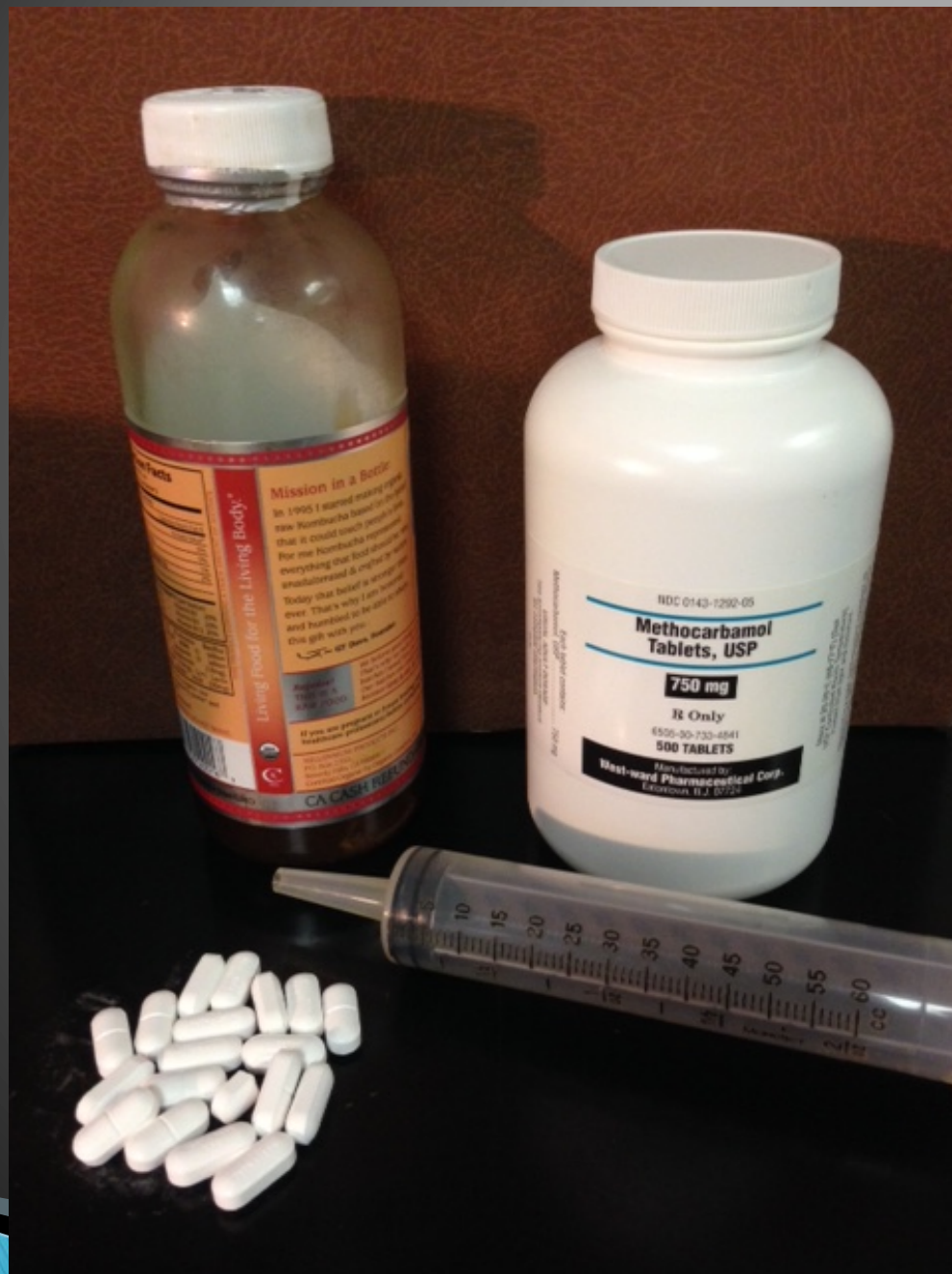
**DORMOSEDAN®**  
ketamine hydrochloride  
Sedative and Anesthetic  
For Use in Horses Only  
Sterile Solution—10 mg/mL  
Contains Federal law restricts this  
drug to sale by or on the order  
of a licensed veterinarian.  
Net Contents: 5 mL  
NADA 141-887  
Approved by FDA

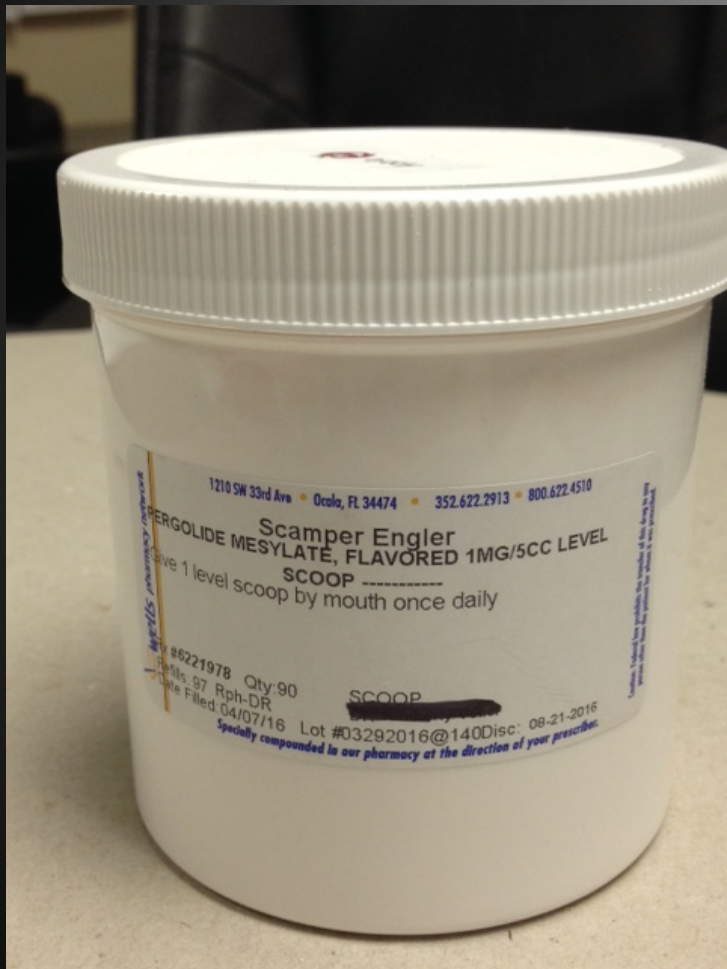
12316

Use/Dosage: Dogs—0.25  
mg/100 lbs of body  
weight. Cats—0.5 mg up  
to 1 mg/10 lbs of body weight.  
Horses—2 mg up to 4  
mg/100 lbs of body weight.  
Refer to folded label  
attached to this container  
before using.  
Store at controlled room  
temperature, 59° - 80°F  
(15°-27°C).  
NDC 57319-447-04  
**Acepromazine  
Maleate Injection**  
**10 mg/mL**  
A Sterile Solution for Intravenous, Intra-  
ocular or Subcutaneous Injection.  
NADA 200-381. Approved by FDA  
**CAUTION:** Federal  
U.S.A. law restricts  
this drug to use by  
or on the order of a  
licensed veterinarian.  
Net Contents:  
10 mL



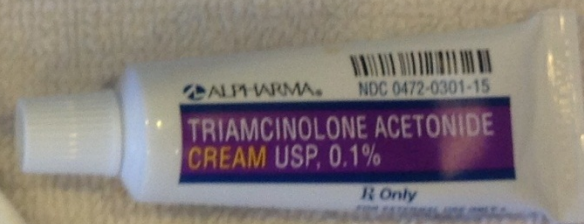






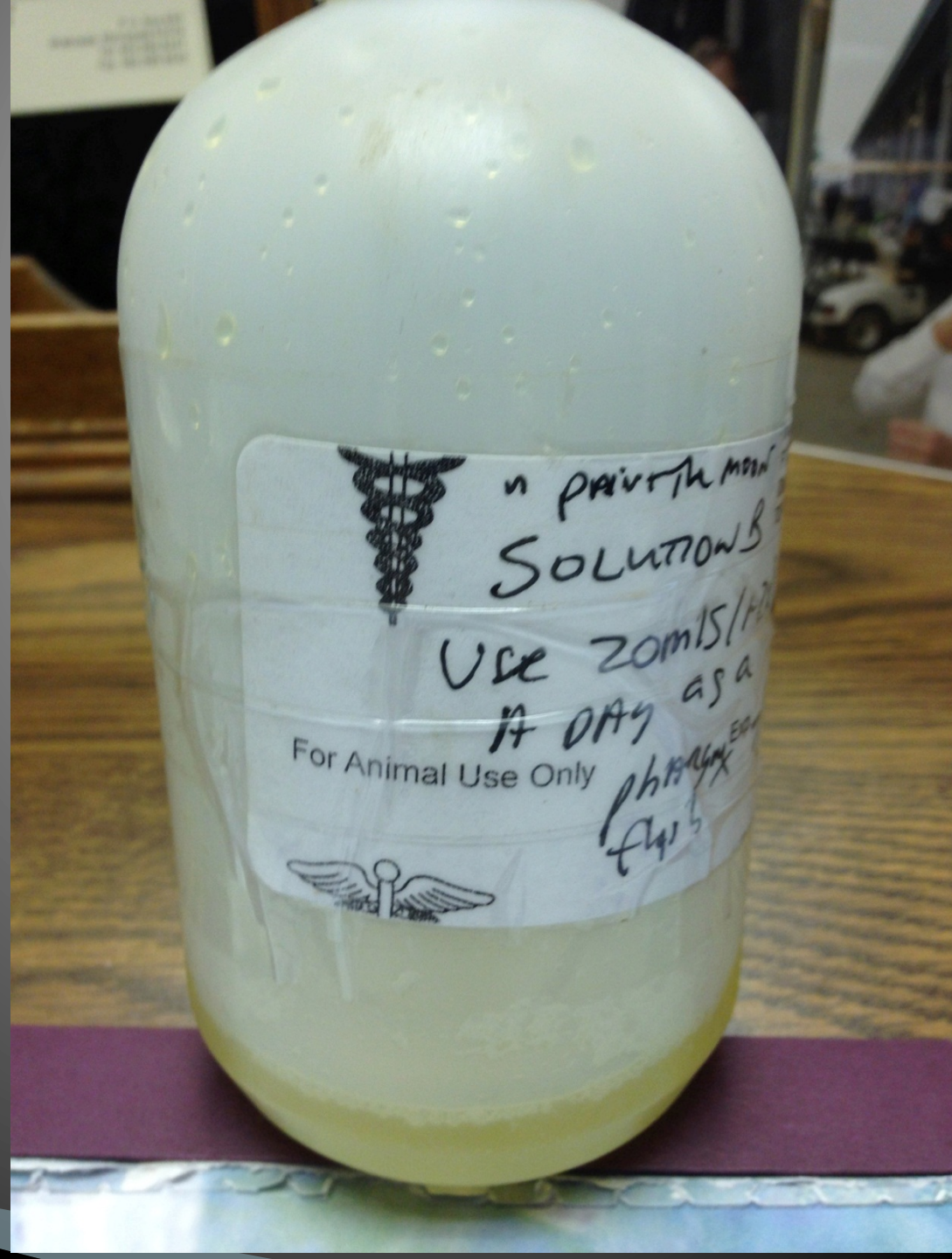


Chlorhexidine  
DMSO  
Furacin  
Griseofulvin  
Dexamethasone  
+  
Triamcinolone





FURACIN  
DMSO  
DEXAMETHASONE



# Discontinued FDA Approved Medications



# Backorder FDA Approved Medications





# Illegal Compounding

- ▶ Bulk drugs used
  - Methylprednisolone not from label products
- ▶ Bulk manufacturing
  - 30 tubes of omeprazole paste
- ▶ Inappropriate labeling
  - Lacks required information
- ▶ Not based on a diagnosis
  - Entire barn is on omeprazole/ranitidine paste
- ▶ No valid patient/client relationship
  - Ordered via the internet

# Methylprednisolone



# Betamethasone



# Amikacin



# Compounding or Illegal New Medication?





# Compounding or Illegal New Medication?

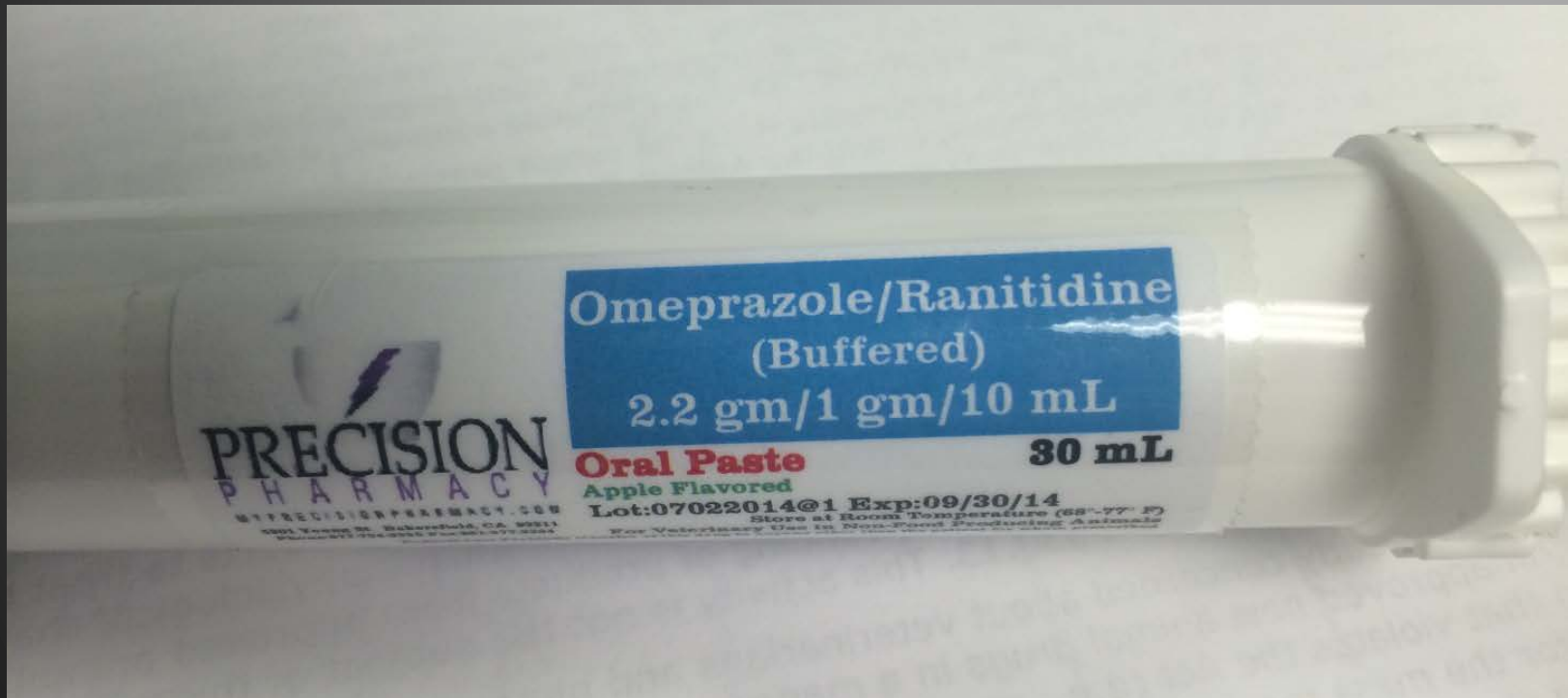
- ▶ Omeprazole + Misoprostol
  - FDA Cease and Desist Issued
  - Sold over the counter directly to trainers
  - Repackaged and still being sold



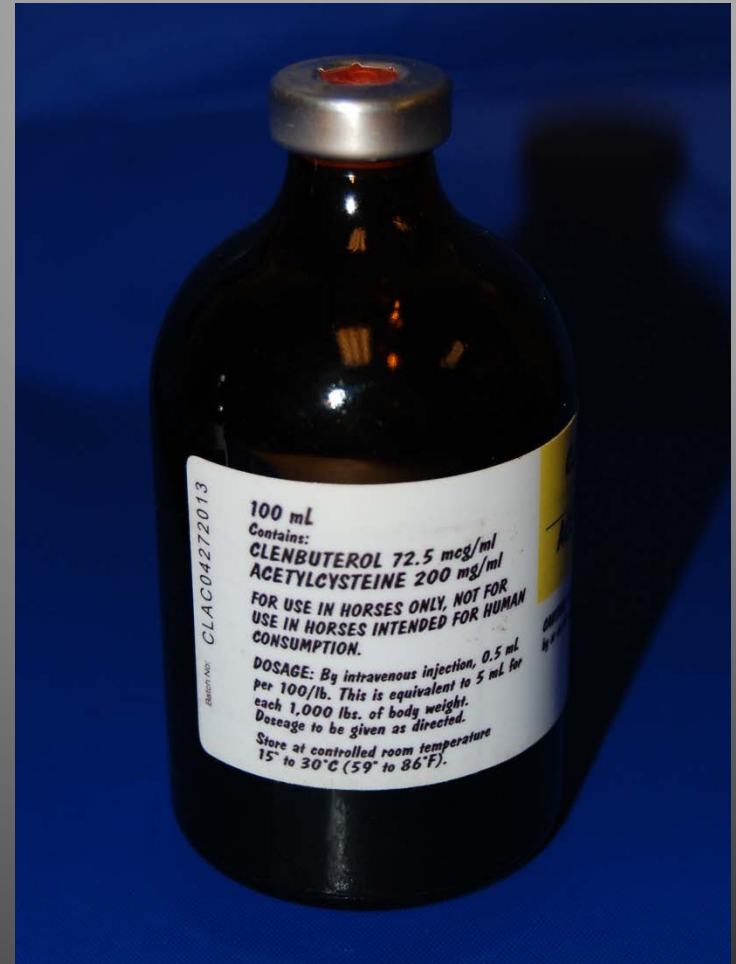
# Pre-Race Bleeder Medication



# Compounding or Illegal New Medication?



# Clenbuterol + Acetylcysteine





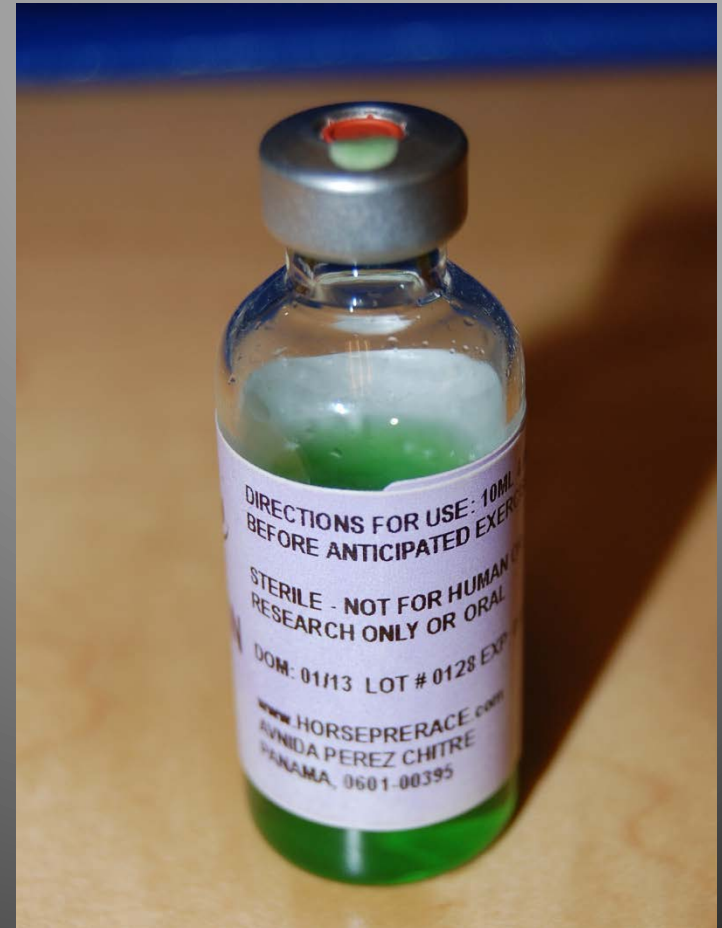
# Ceftiofur + Butafosfan



# Triamcinolone + Amikacin



# Purple Pain





# 5000

**EVIDENCE/PROPERTY**

Agency ANRC Case No. 420772  
Item No. 1 Offense \_\_\_\_\_  
Suspect \_\_\_\_\_  
Victim \_\_\_\_\_  
Date and Time of Recovery 6/28/13  
Recovered By James J.  
Description and/or Location Unknown  
Substance: (OXY & SDO)

**CHAIN OF CUSTODY**

| FROM            | TO             | DATE           |
|-----------------|----------------|----------------|
| <u>James J.</u> | <u>McDAVIS</u> | <u>6/28/13</u> |
|                 |                |                |
|                 |                |                |
|                 |                |                |
|                 |                |                |
|                 |                |                |

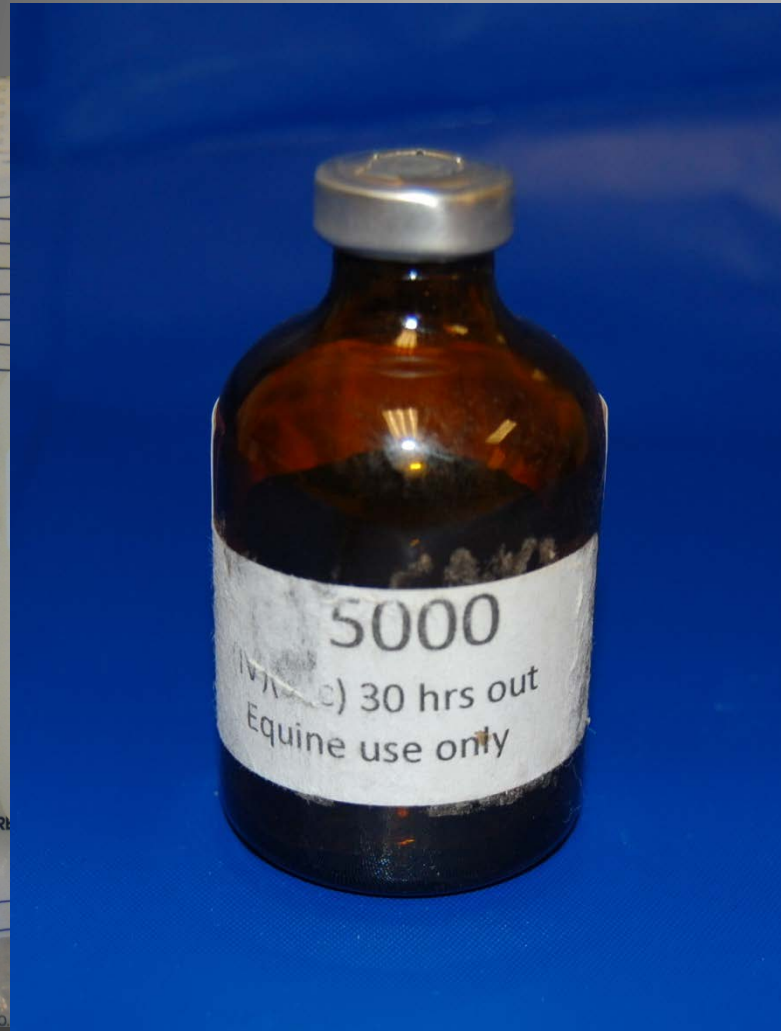
**TO USE:**  
1) Remove Release Liner from Flap.  
2) Fold Where Indicated. BAG IS NOW SEALED.  
3) Tear Where Indicated and Retain Evidence Receipt.

**CAUTION: ATTEMPTS TO REOPEN WILL DISTORT SEALED AREA.**

CONDITION OF BAG WHEN OPENED: ☐ SEALED  
☐ OTHER \_\_\_\_\_

OPENED BY \_\_\_\_\_ DATE \_\_\_\_\_

**SIRCHIE®** Products • Vehicles • Training  
100 Hunter Place, Youngsville, N.C. 27596 U.S.A.  
Phone: (919) 554-2247, (800) 356-7311  
Fax: (919) 554-2266, (800) 899-8181



**EVIDENCE/PROPERTY**

Case No. 0773  
Date 6/28/13  
Description Substance: (OXY & SDO)

**CHAIN OF CUSTODY**

| FROM | TO | DATE |
|------|----|------|
|      |    |      |
|      |    |      |
|      |    |      |
|      |    |      |
|      |    |      |

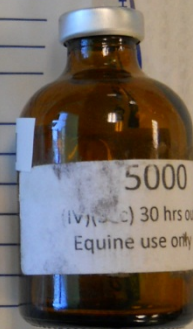
**TO USE:**  
1) Remove Release Liner from Flap.  
2) Fold Where Indicated. BAG IS NOW SEALED.  
3) Tear Where Indicated and Retain Evidence Receipt.

**CAUTION: ATTEMPTS TO REOPEN WILL DISTORT SEALED AREA.**

CONDITION OF BAG WHEN OPENED: ☐ SEALED  
☐ OTHER \_\_\_\_\_

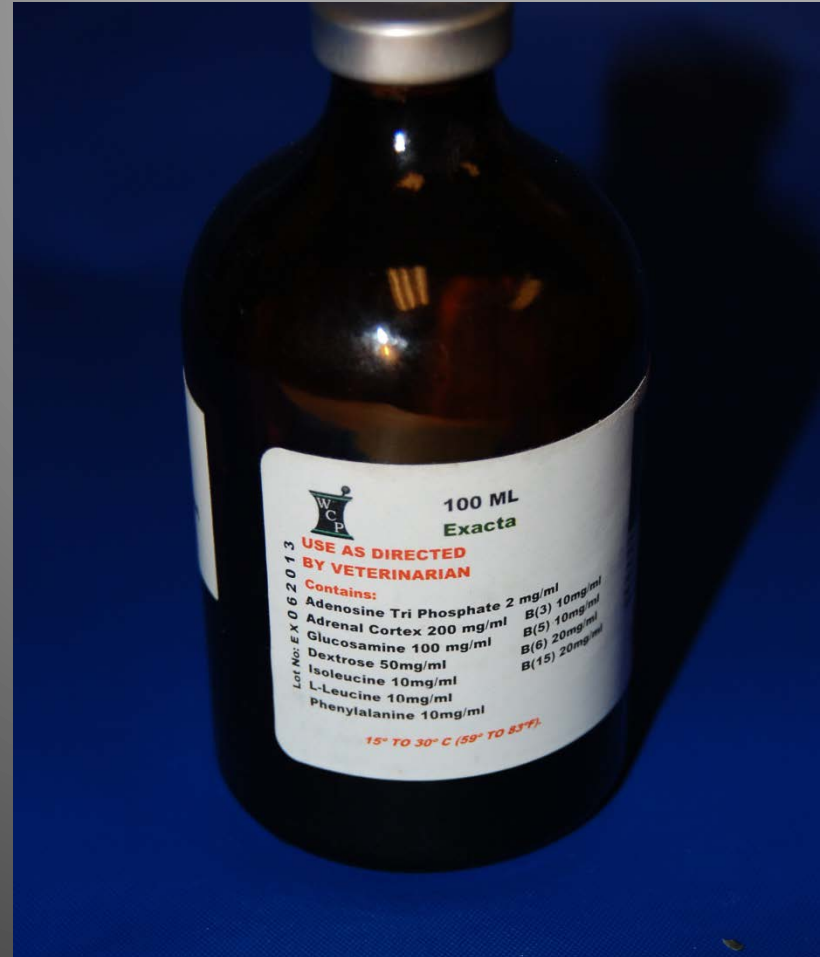
OPENED BY \_\_\_\_\_ DATE \_\_\_\_\_

**SIRCHIE®** Products • Vehicles • Training  
100 Hunter Place, Youngsville, N.C. 27596 U.S.A.  
Phone: (919) 554-2247, (800) 356-7311  
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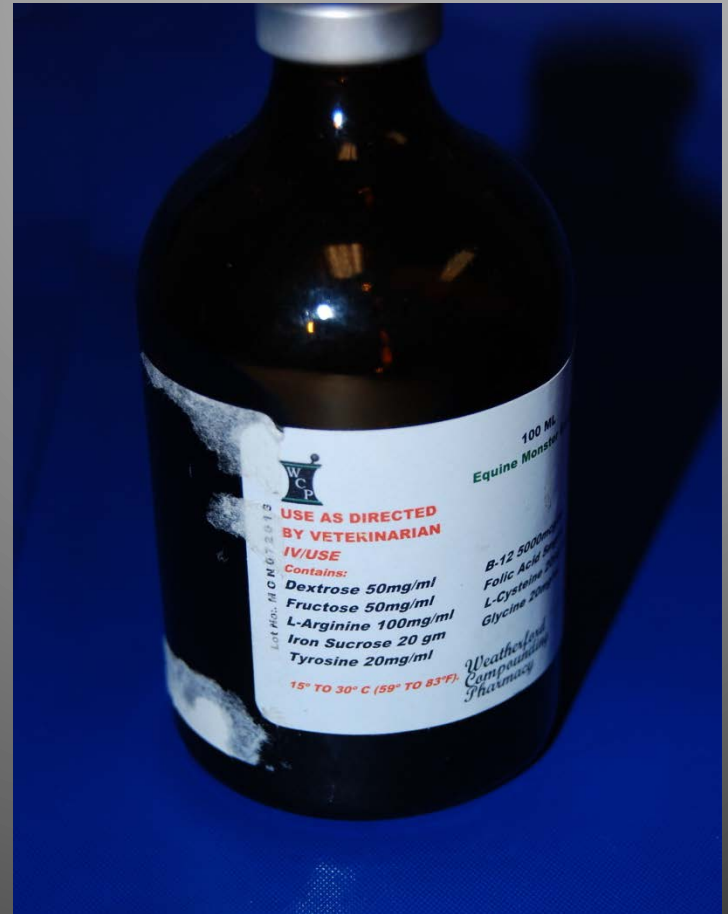




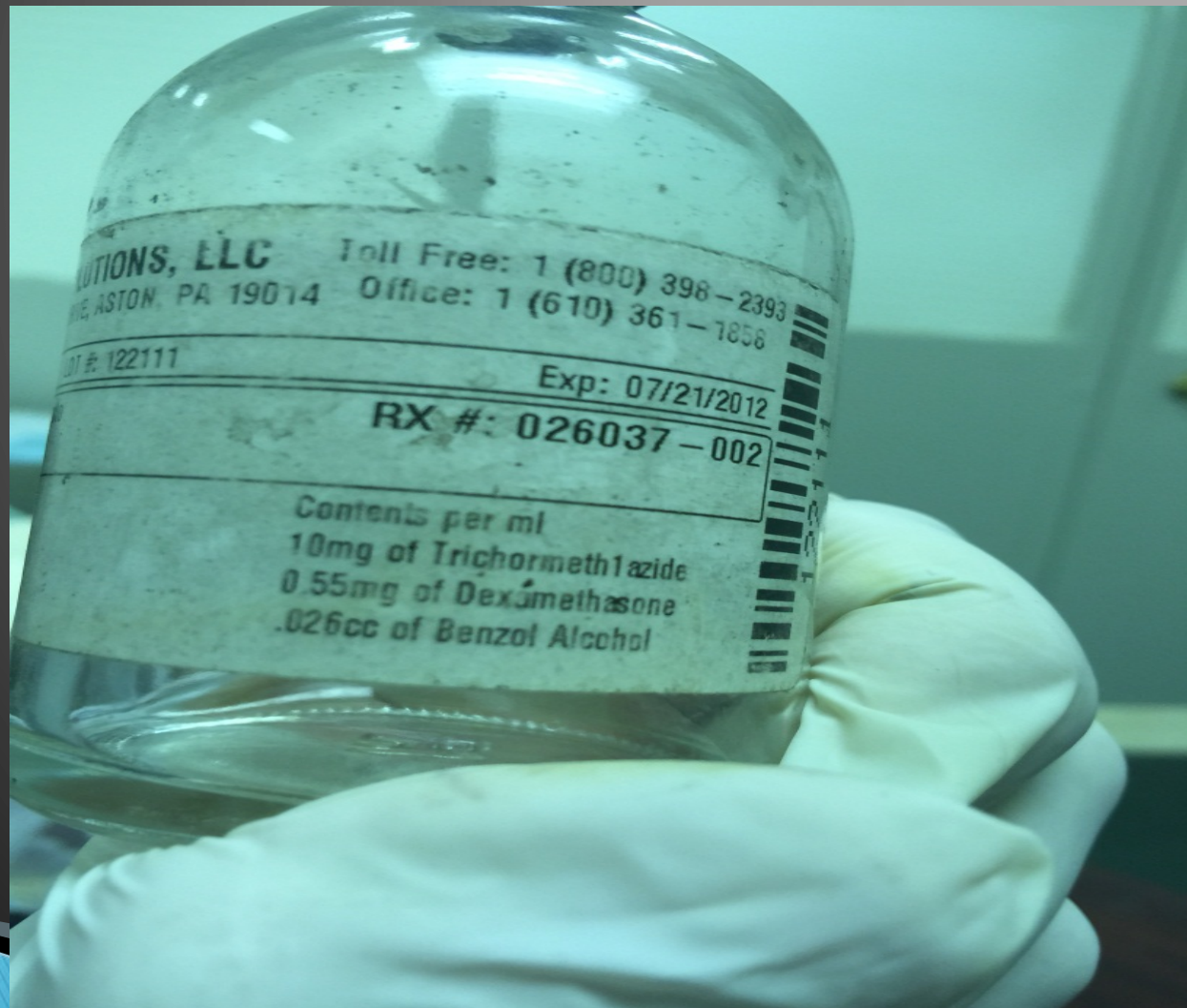
# Exacta



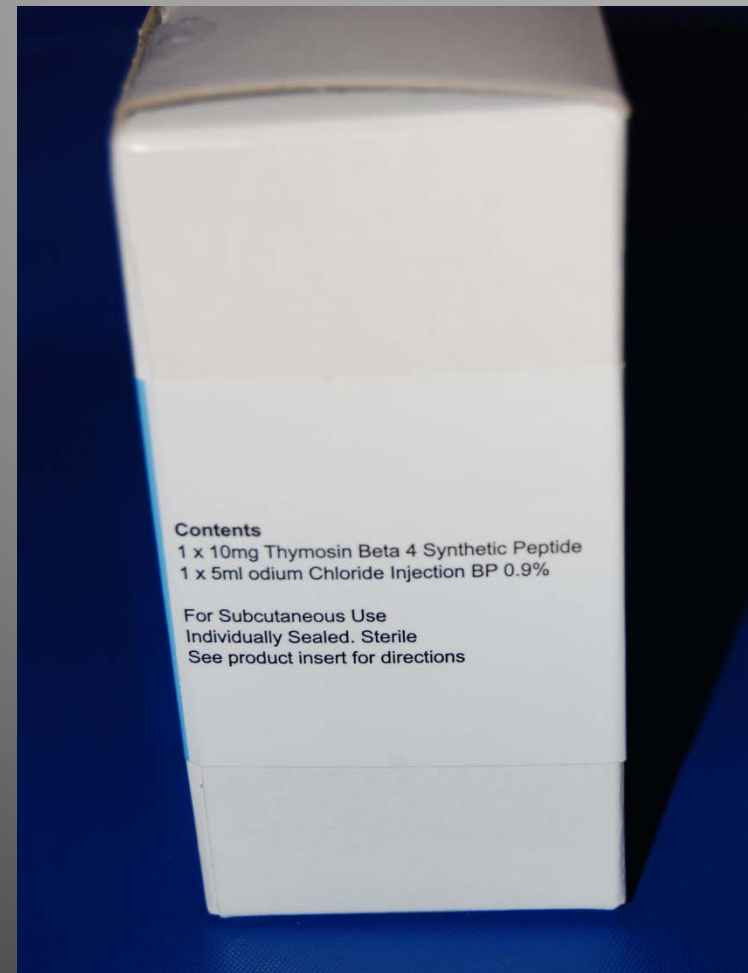
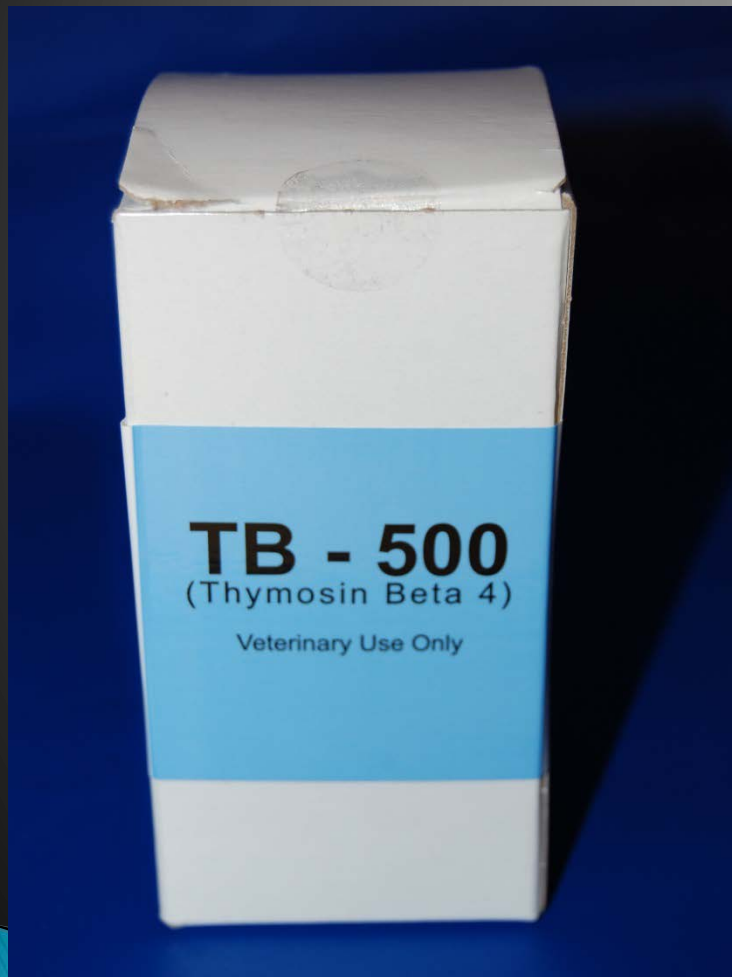
# Equine Monster Energy



# Trichlormeth + Dexamethasone

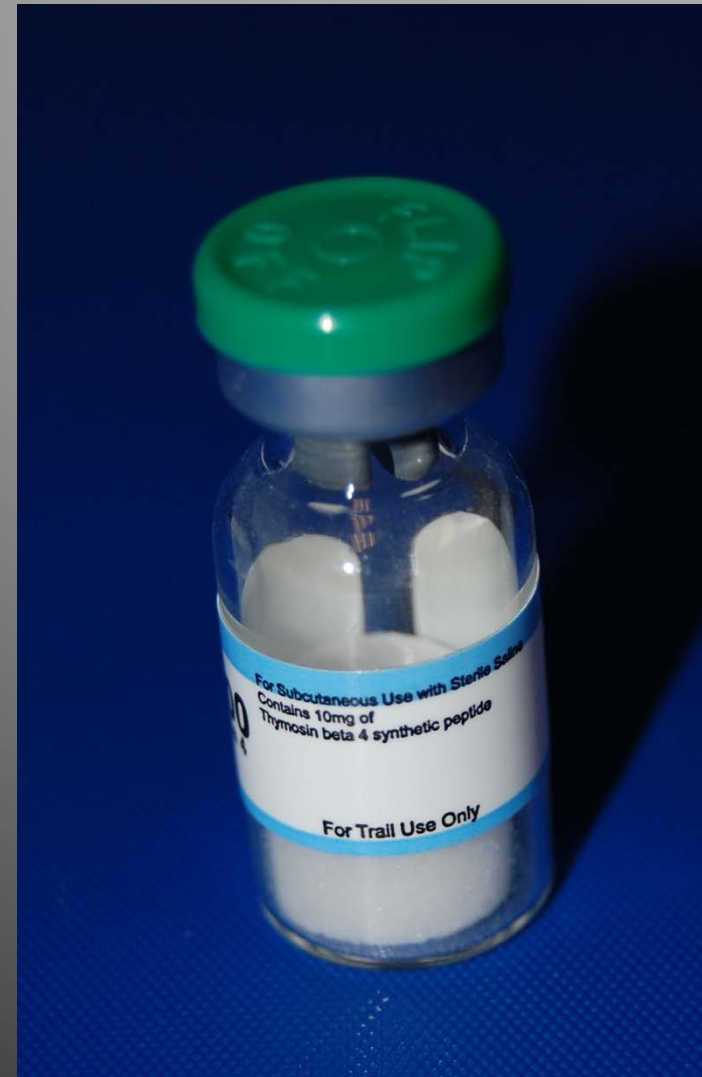
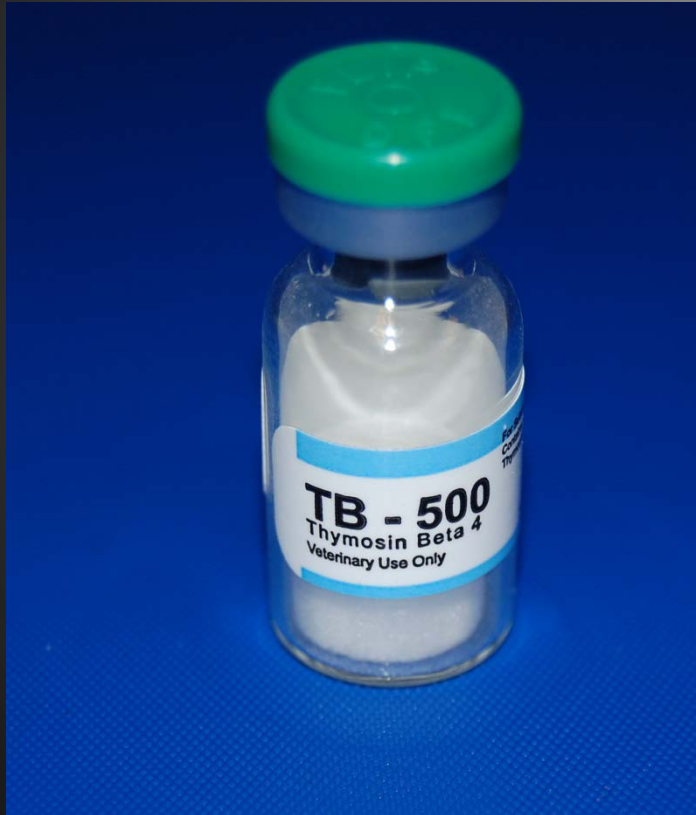


# TB-500

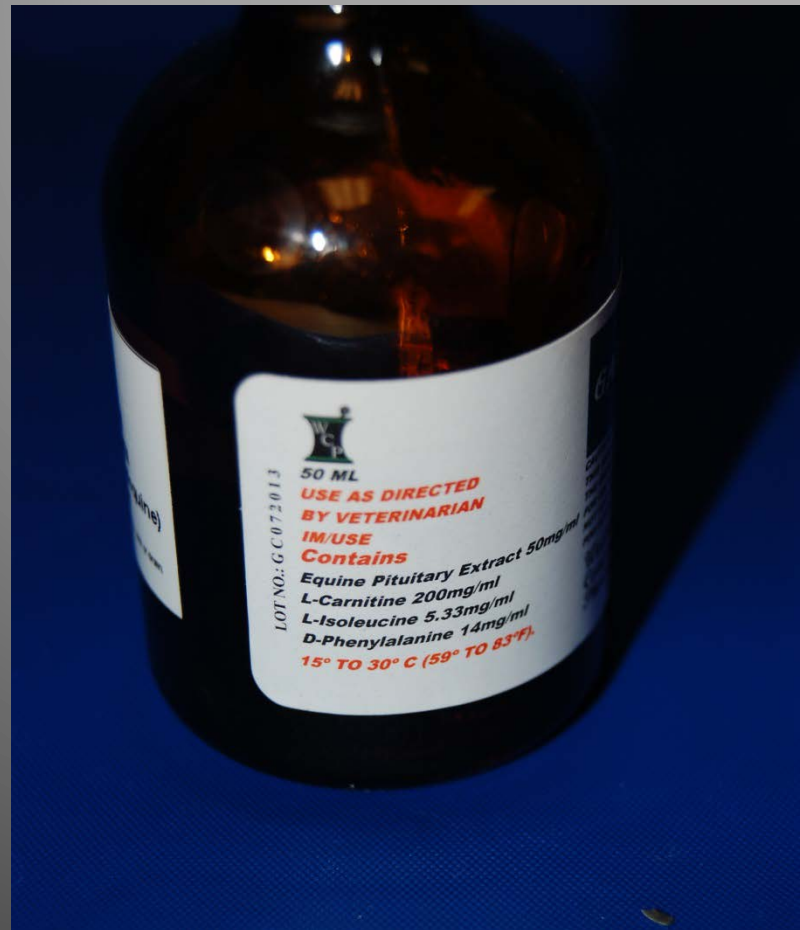




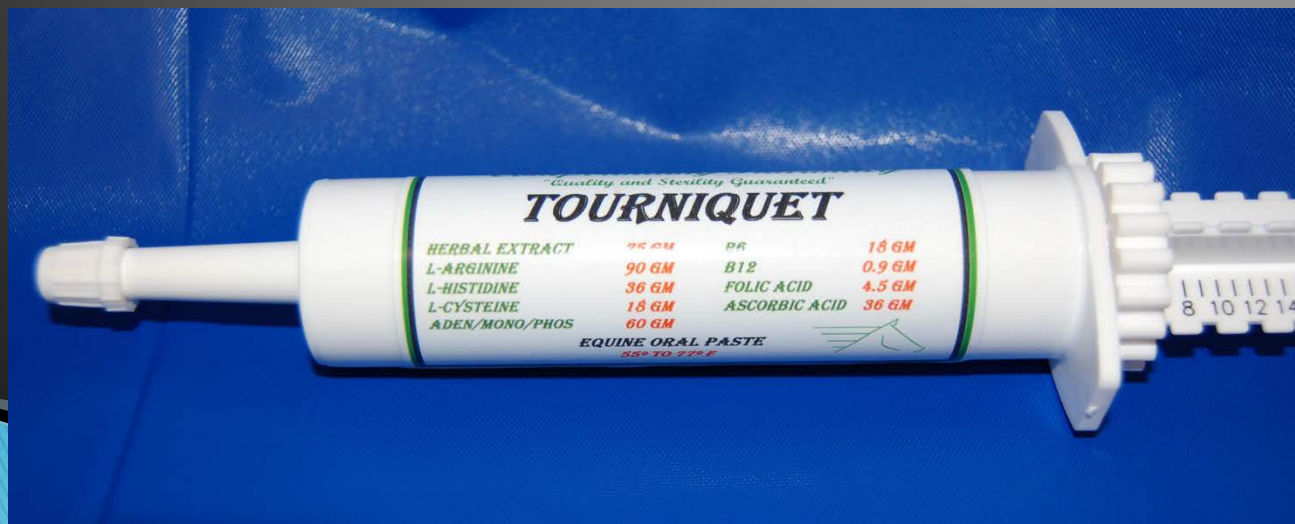
# TB-500



# Game Changer



# Oral Paste – Amino Acids

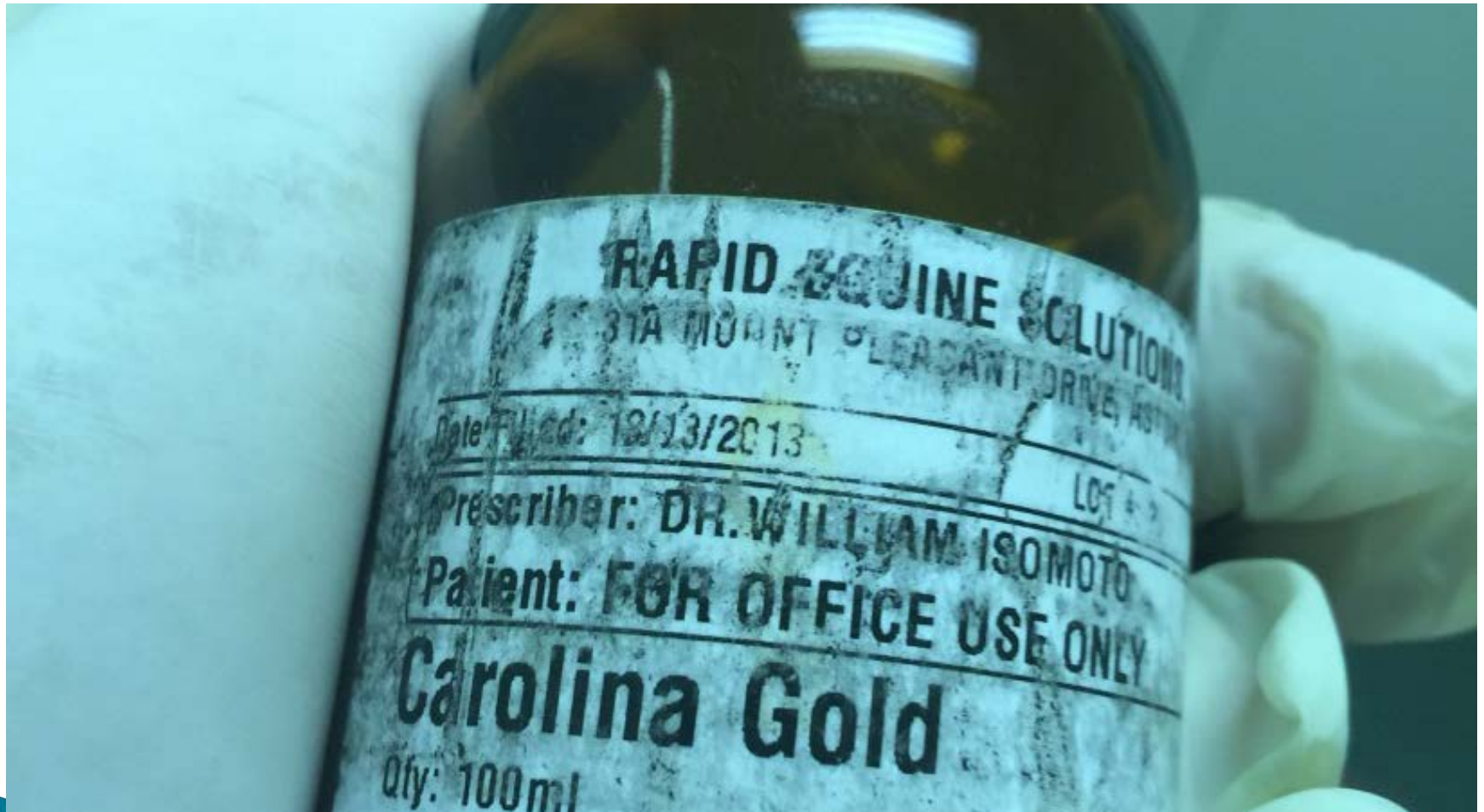


# Carolina Gold (GABA)



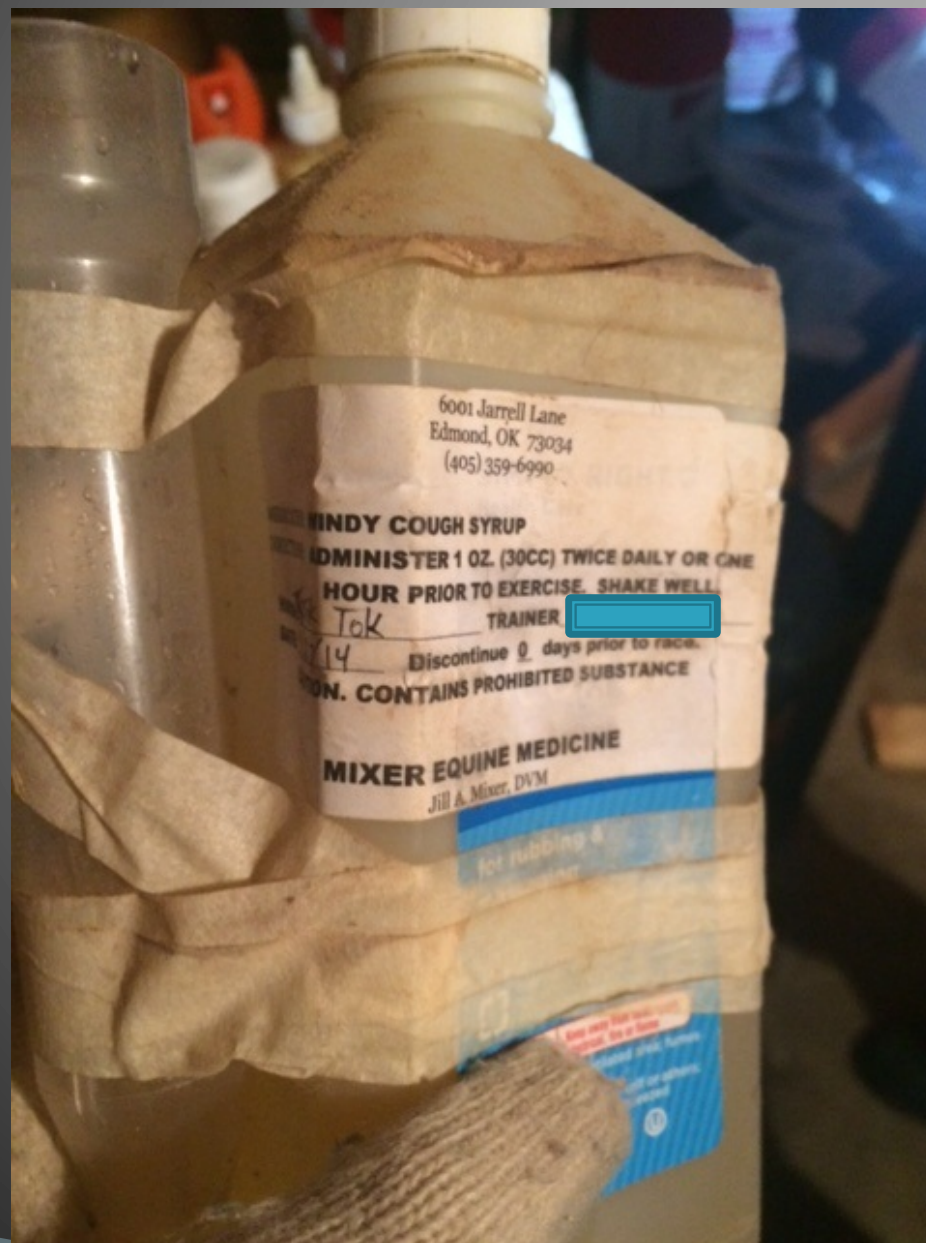


# Carolina Gold



# Stop Two



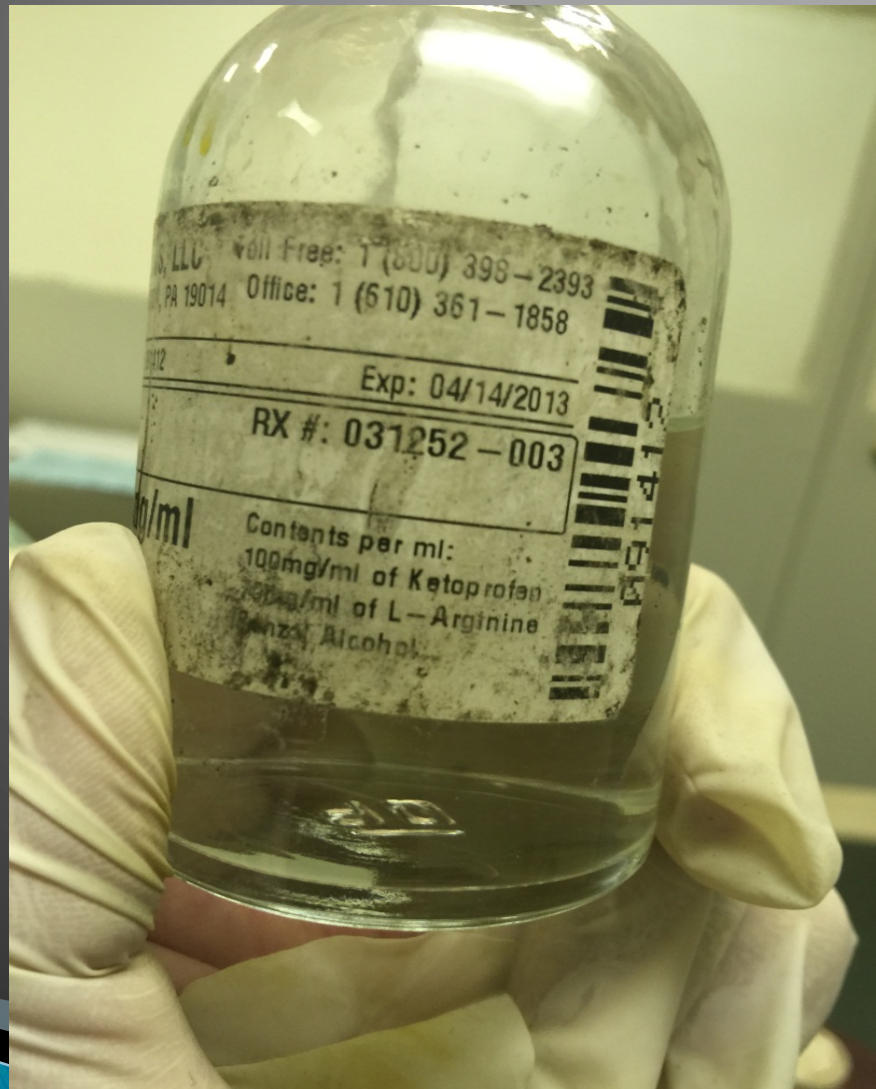


# Bleeder Stop 2 + 7





# Ketoprofen + L-Arginine



# Compound 150



# Equine Growth Hormone







**SODIUM CHLORIDE**  
**0-500 A.S.**

**INTRAVENOUS INJECTION**  
**OXYGEN PRODUCT**  
for veterinary use only

**100 ML IV Multiple**

**STERILIZED WITH OZONE**

Recommended Use 1/2-1 (ml)  
100 lbs. body weight plus same amount



# Ketoprofen + Glucosamine + Pentosan



# Cacodylate + Strychnine







# Bleeder O

Shake well, store in a cool, dark place.  
Remove excess air after each use

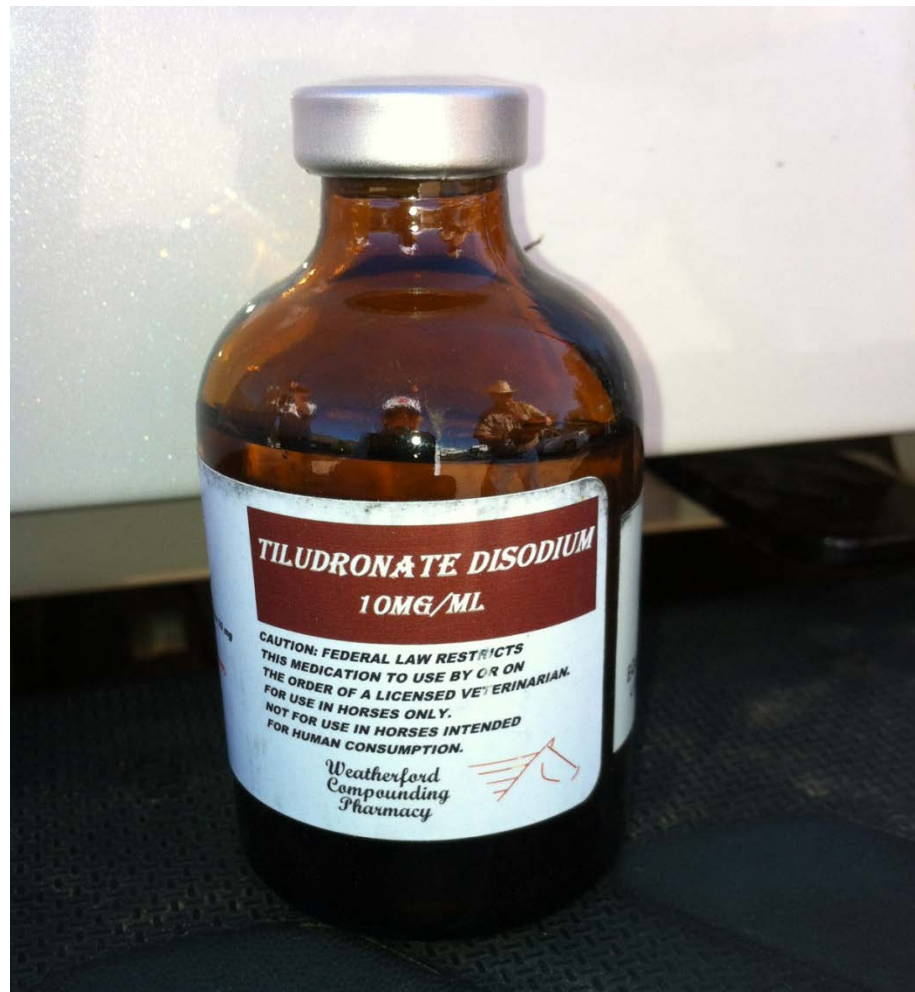
FOR EQUINE USE ONLY  
NOT FOR USE IN ANIMALS INTENDED FOR MEAT OR HIDE  
KEEP OUT OF REACH OF CHILDREN

Expires 12/2012

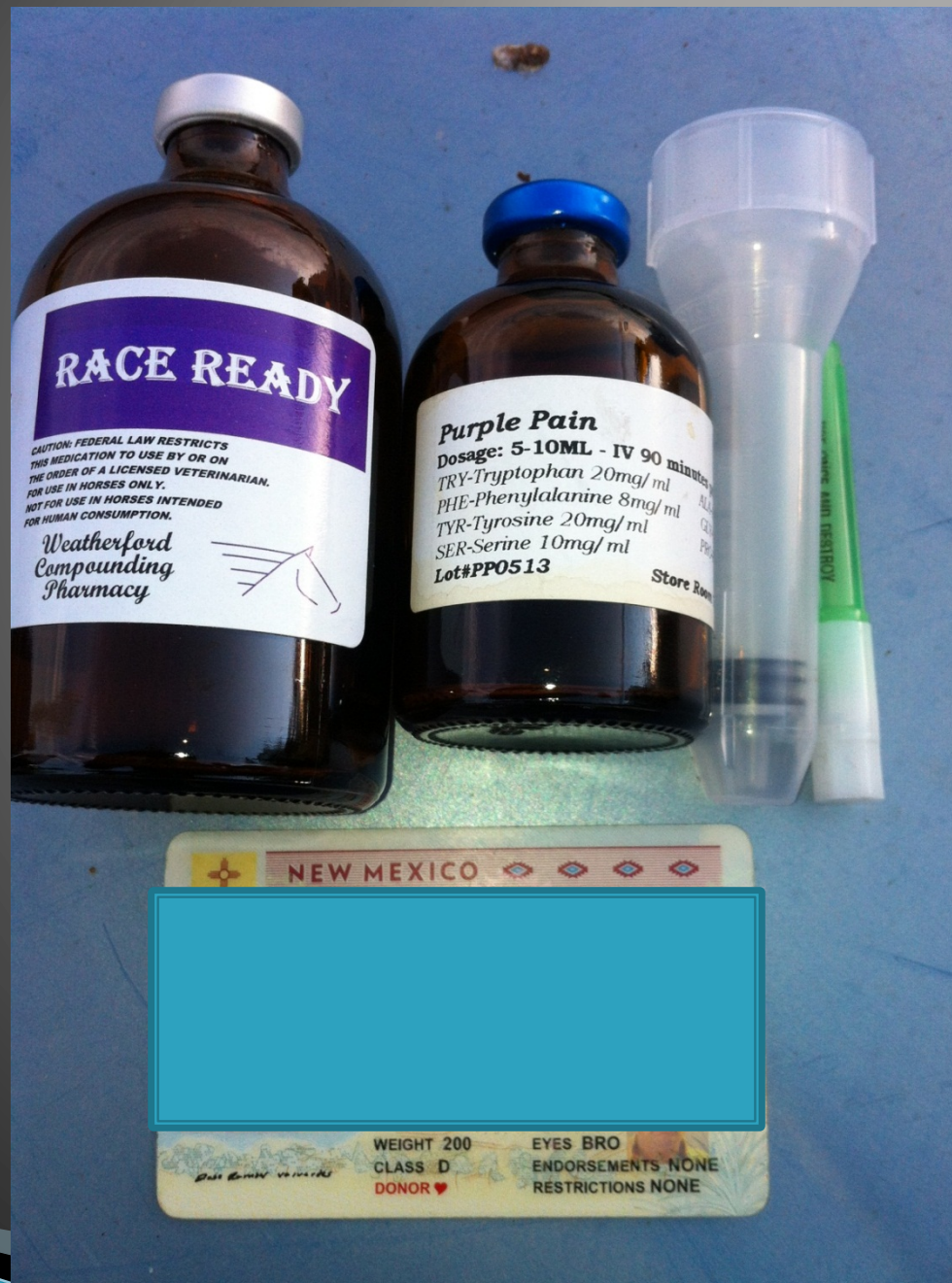
CAUTION: Federal law restricts this product to use by or on the order of a licensed veterinarian

NET CONTENTS: 100 mL

# Tildronate Disodium







## RACE READY

CAUTION: FEDERAL LAW RESTRICTS THIS MEDICATION TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. FOR USE IN HORSES ONLY. NOT FOR USE IN HORSES INTENDED FOR HUMAN CONSUMPTION.

Weatherford  
Compounding  
Pharmacy



## Purple Pain

Dosage: 5-10ML - IV 90 minutes  
TRY-Tryptophan 20mg/ml  
PHE-Phenylalanine 8mg/ml  
TYR-Tyrosine 20mg/ml  
SER-Serine 10mg/ml  
Lot#PP0513

Store Room

NEW MEXICO

WEIGHT 200  
CLASS D  
DONOR

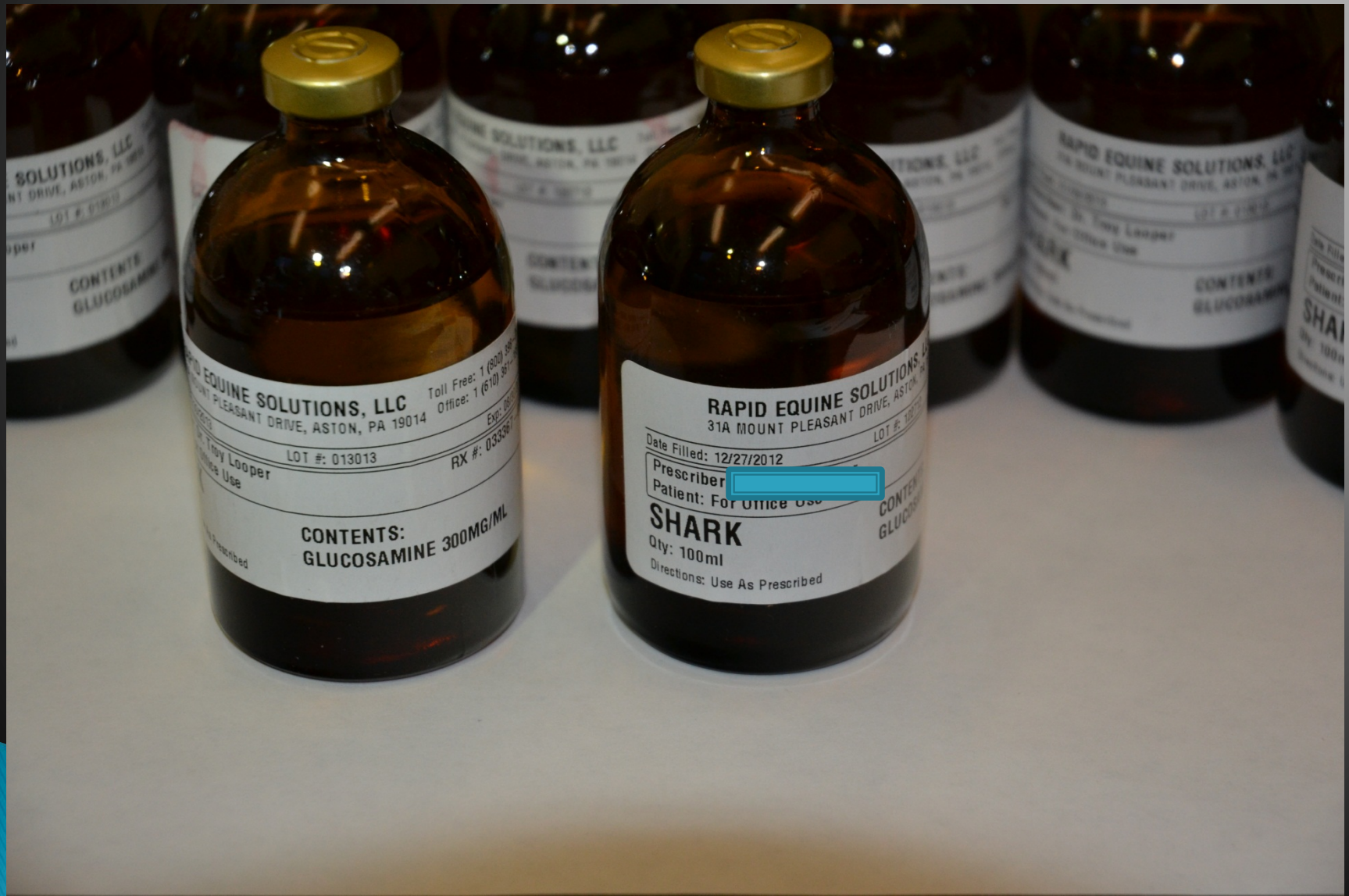
EYES BRO  
ENDORSEMENTS NONE  
RESTRICTIONS NONE

# Nebraska Gold

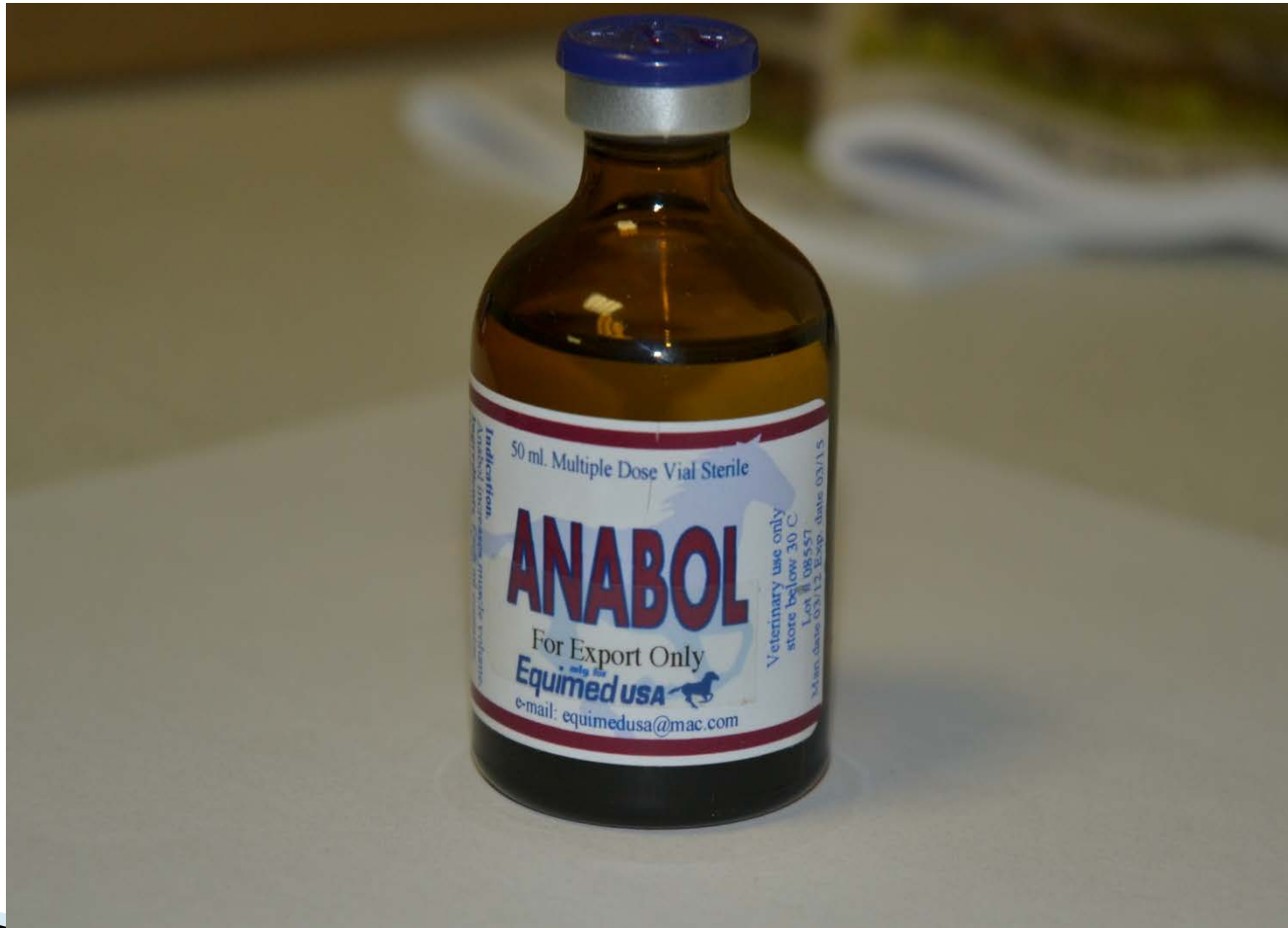




# Shark



# Anabol





# Keto-San Gold



Thank You