

Animal Health Industry -Unapproved Veterinary Drugs-

USP Veterinary Drugs Stakeholders
Forum

November 2012



Background

- There are a number of unapproved animal drugs being marketed
 - No FDA review and approval
- FDA recently published a Federal Register Notice in which they are seeking comments on strategies for finding legal “homes” for unapproved products.



Unapproved drugs

- Unapproved drugs have not been approved by the Food and Drug Administration and are being illegally marketed in the United States
 - This means...
 - The safety and efficacy of these drugs has not been established
 - No assurance that the product is tested to meet a specification that ensures the quality, purity, potency of the product
 - No assurance that the product was manufactured in a suitable facility
 - No FDA oversight of the product
 - No inspections of domestic or foreign facility
 - No post-approval monitoring to ensure product performance



“Categories” of Unapproved Drugs

- Unapproved drugs filling a need not met by currently approved products
- Unapproved drugs that are being commercially sold as formulations comparable to approved animal drugs
- Unapproved drugs that are being commercially sold under the guise of being a generic
- Unapproved drugs manufactured under the guise of compounding



Unapproved Drugs

- Unapproved drugs filling a need not met by currently approved products that have been available for many years without significant problems
 - Industry Perspective
 - Industry agrees with the goal of CVM to try and increase the number of approved or legally marketed animal drugs
 - Industry does not believe that the bulk of unapproved animal drugs fall under this category



Unapproved Drugs

- Unapproved drugs that are being commercially sold as formulations comparable to approved animal drugs
- Unapproved drugs that are being commercially sold under the guise of being a generic
- Unapproved drugs manufactured under the guise of compounding
 - Industry Perspective
 - AHI members are most concerned about these products.
 - Widespread problem with numerous companies and compounding pharmacies selling numerous products in clear violation of the FD&C Act
 - AHI members are concerned that these products are being promoted as equivalent or superior to FDA approved animal drugs



Examples

- Unapproved drugs that mimic approved drugs
 - Gastromax
 - Lomac Equine
 - Abprazole Plus
 - Pentosan
 - Ablver Plus



Gastromax

– E-mails from Gastromax Representative

- “Independent clinical and onsite studies has been performed and this product has passed **100% everytime**, on every scope, for healing ulcerated stomachs in equine's. These tests were performed by recognized vets and done at the stables of leading reputable trainers,winning their approval. The product is also patent pended and is **USP Grade Omeprazole Certified**. This product is Lab Tested and Approved by Adamson Lab in California...”
- “Much like Succeed, U7 and other top selling products, **we did not FDA approve the product**, but like those others we also used **an FDA approved lab to certify the product and it's ingredients. This meaning it is USP Grade** and has what we claim it has in the right dosage per ingredient etc. **By not having it FDA, is saves us millions of dollars and a lot of red tape (keeping costs down over the competitors), but it is just as potent and effective as the FDA registered ones.**That is the info listed on the email I sent, introducing the product and the link to Adamson Lab, California. I guess that most customers when they buy a product do not look to see if it is FDA approved, but rather assumes that it does what it says and put their trust in the product name...”



Lomac Equine

– Information from receipt

- Gastrogard 37% 14 Syringe of 6.15gms – Generic

– Information from website

<http://otcvetmeds.blogdumps.net/2011/09/14/generic-gastrogard-syringe-lomac-equine-by-cipla/>

- “Generic Gastrogard syringe-Lomac Equine from Cipla is best to treat and prevent the recurrence of gastric ulcers in horses and foal that are four weeks of age or older.”



Abprazole Plus

- Information from website www.abler.com
 - “Omeprazole is the only treatment for EGUS currently approved by the Food and Drug Administration (FDA).”



Pentosan

- Information from website www.pentosan.com
 - PENTOSAN EQUINE actively reverses the effects of osteoarthritis in the joints via a series of actions
 - PENTOSAN EQUINE is NOT a non-steroidal anti-inflammatory drug like Phenylbutazone, or the cortisones (both of which have damaging effects on joints with prolonged use).
 - PENTOSAN EQUINE does not suppress joint cartilage healing and repair.
 - Rather than simply masking pain, PPS directly stimulates joint healing and repair.
 - Anti-inflammatory agents, corticosteroids and NSAIDs all relieve the symptoms of osteoarthritis but DO NOT ALTER THE DISEASE PROCESS. Both hydrocortisone and NSAIDs have a marked inhibitory effect on the biosynthesis of the components of the extracellular matrix of cartilage, which limits the early healing response of cartilage to injury.



Ablver Plus

- Information from website www.abler.com
 - “**Ablver Plus™** Two-in-One broad spectrum equine dewormer - combining Ivermectin and Praziquantel in granule form. Provides maximum worm control in a single dose.”
 - “Praziquantel, a member of the pyroazine group of pharmaceutical active compounds, showing selective effectiveness against all three species of equine tapeworms: *p.mamillana*, *magna*, and *perfoliata*.”
 - Note: Approved products only have label claims for one species of tapeworm (*A. perfoliata*)



Industry Concerns

- Products are promoted as equivalent or superior to an FDA approved drug product
- Products that should require a prescription are available directly to the consumer without veterinary intervention
- Products are marketed as being USP Grade
 - Gives credence to the product since USP is the officially recognized standard
 - Is there anything that USP can do to clarify that:
 - USP Grade \neq FDA approved product
 - USP Grade \neq USP verified/inspected
- Products are marketed as using FDA approved testing facilities
- Products imply FDA approval



Thank you

