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GENERIC ANIMAL DRUG ALLIANCE

Reauthorization of the Animal Generic Drug User Fee Act

Public Meeting

November 2, 2017

Rockville, MD

Bill Zollers, GADA Chair

Generic Animal Drug Alliance

An independent professional trade association serving organizations with interests in generic animal drug products.

GADA represented the generic animal drug industry in user fee negotiations with CVM for both AGDUFA I, AGDUFA II and AGDUFA III.

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Our Sponsor Members

AgriLabs, Ltd.
AmPharmCo, Inc.
Bayer Healthcare Animal Health, Inc.
Bimeda North America, Inc.
Ceva Animal Health, LLC
Cook Animal Health, Inc.
Cronus Pharma LLC
Dechra Ltd.
e5Pharma, LLC
First Priority, Inc.
Huvepharma, Inc.
Med-Pharmex, Inc.
Norbrook, Inc.
Pegasus Laboratories, Inc.
Perrigo Animal Health
Pharmgate, LLC
Provetica Animal Health
Quo Vademus LLC
Sparhawk Laboratories, Inc.
Vetoquinol USA Inc.
Virbac Corporation

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Our Associate Members

- Argenta Limited
- Chemwerth, Inc.
- Flavine North America, Inc.
- Herschel J. Gaddy & Associates
- Knotty-Tide Consulting, LLC
- Piedmont Animal Health
- PPD
- Qilu Pharmaceutical
- Rochem International, Inc.
- Univar
- VetPharm, Inc.

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Benefits of Generic Animal Drugs

- Provide pet owners and producers with cost-effective choices that are as safe and effective as the pioneer products
- Shorten the innovation cycle by encouraging pioneer companies to develop new products/technologies

87% of pet owners would likely choose an FDA approved veterinary generic if one was available,[1] but only 10% of pioneer drugs for pets have an approved generic version[2]

[1]Critical Insights independent market survey of 1000 pet owners, May 2015

[2]GADA member company review of animaldrugs@fda.gov, Fall 2015

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Challenges Affecting Generic Animal Drug Approval and Availability

- Time from Project Inception to Approval
- Costs of Meeting Increasing Regulatory Requirements
- Lack of Published Generic Drug Regulations
  - Creates regulatory uncertainty for the Sponsor/possible CVM policy changes
- Demonstrating Bioequivalence
  - Multi-species labels require studies in each species for initial approval
  - Need creative regulatory path for some products (e.g. bioequivalence by *in vitro* or clinical endpoint?)
- Illegal Pharmacy Compounding
  - Creates unfair competition from products that have no assurance of safety, effectiveness or quality

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AGDUFA III – Industry Perspective

- Industry agrees that the Year 1 base of $18,336,340 should allow for appropriate capacity building within CVM for a sustainable regulatory review program while meeting the shorter review timeframes
- The success of the CVM Generic regulatory program continues to rely on Congressional and FDA agency support through appropriations
- The new shorter regulatory review cycle timeframes are in line with current CVM standard for pioneer products
- The financial terms of Overcollections and Offsets have been adjusted appropriately to ensure all funds received from user fees are accessed and utilized quickly for achieving AGDUFA III goals

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AGDUFA – Future Challenges

- Maintain an affordable, sustainable regulatory review program, which meets or exceeds agreed upon review timeframes (i.e. do not go backwards in AGDUFA IV)
- The generic review process can only be sustainable with continued Congressional and FDA agency support through budget appropriations
- Continue financial terms that allow user fee funds to be utilized quickly
- Increase communication/amendments during the review cycle between CVM and the Sponsor
- Balance regulatory reform with recent interpretations of regulations that has led to increased requirements

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AGDUFA – Future Challenges

- CVM achievement of AGDUFA Goals does not necessarily equate to new approvals. Therefore, industry may lose confidence in the AGDUFA program.
- The challenge is to be sure that as CVM User Fees continue to increase so does the availability of new approved veterinary generic drugs for consumers.

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