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GENERIC ANIMAL DRUG ALLIANCE

Generic Animal Drug Alliance: Reauthorization of the Animal Generic Drug User Fee Act (AGDUFA)

Public Meeting

May 16, 2016

Rockville, MD

Jennifer Johansson, 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 and AGDUFA II.

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Our Members

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

Associate Members:

Aratana Therapeutics, Inc.
Argenta Limited
Chemwerth, Inc.
Flavine North America, Inc.
Herschel J. Gaddy & Associates
Nutramax Laboratories, Inc.
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 to Approval
- Costs of Meeting Increasing Regulatory Requirements
- Demonstrating Bioequivalence
  - Need for studies in >1 species
  - No bioequivalence path for some products (stalling of *in vitro* bioequivalence path)
- Illegal Pharmacy Compounding
  - Creates competition from products that have no assurance of safety, effectiveness or quality
- API Availability/Import Alerts

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AGDUFA Experience

Overall, AGDUFA has brought positive change

- Allows “acceptable” review times despite Congressional appropriation shortfalls
- Provides regulatory process predictability
- Keeps review cycle times shorter
- Allows for beneficial process improvements

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AGDUFA Experience

But industry struggles with ever-increasing fee burdens, while review time goals remain constant

AGDUFA	Fiscal Year	ANADA Fee	Review Cycle Goal
I, first year	2009	41k	700 days
I, final year	2013	148k	270 days
II, current	2016	233k	270 days

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AGDUFA Experience

As CVM workload has increased sponsors report noticeable ill effects in review performance

- Fewer perceived opportunities for application amendments and for communications with CVM
- Sponsors experience the repercussions of increased CVM workload despite significant fee increases from workload adjustor (30% in FY 2016, 18.8% in FY 2015)
- Unclear where fees are going and how they are being used (FY 2014 Financial Report: $10m carryover including $2m collected but “unavailable”)

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AGDUFA III Needs

- Keep fees down by finding review process efficiencies
- Shorten time to approval by implementing process enhancements
- Increase beneficial communication between CVM and industry
- Adjust financial terms of AGDUFA to ensure all funds received from industry user fees are accessed and utilized for achieving AGDUFA goals

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