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April 19, 2011

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Electronic Submission – <http://www.regulations.gov>

Re: Docket No. FDA-2010-N-0528, Unapproved Animal Drugs

The **Generic Animal Drug Alliance** (GADA) is an independent professional trade organization that represents the interests of generic animal health companies before Federal regulatory agencies and Congress. Many of our member companies have a vested interest in the marketing of currently Unapproved Animal Drugs<sup>1</sup> and our organization acknowledges the necessity of these products in meeting the health needs of both companion and food animals.

Joining GADA in support of the comments presented here is the **American Veterinary Distributors Association** (AVDA), a not-for-profit corporation, established in 1976 as the national trade organization for businesses engaged in the distribution of animal health products. AVDA members distribute animal health supplies to some 60,000 veterinarians practicing in approximately 30,000 animal health clinics throughout the United States. AVDA Distributor members represent 95% of the animal health industry distributors in the United States. AVDA's membership also consists of manufacturers of animal health products that include pharmaceuticals, supplements, biologicals, white goods, instruments and equipment, and pet foods. In addition, some AVDA member companies also serve the OTC market, made up of farm and feedlot operations, poultry producers, farm stores, etc. For more information about AVDA, visit [www.avda.net](http://www.avda.net).

For the purposes of these comments, we are recognizing the difference between “Unapproved Animal Drugs” and drugs resulting from the practice of pharmacy compounding. While certainly pharmacy compounding, within the legal bounds, serves a purpose in animal health, we believe these legally compounded products are outside the current discussion, in that there is already a pathway established for

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<sup>1</sup> For the purposes of these Comments, “Unapproved Animal Drugs” are those unapproved animal drugs for which CVM is seeking legal marketing status, such as those that are the standard of care for treating animals, those essential to protecting animal health, or those that do not pose safety risks.

these products. We understand that a legitimate process for Unapproved Animal Drugs should ultimately lead to better enforcement against illegal pharmacy compounding.

We appreciate the need for balance between the use of existing systems and processes while employing creative solutions for approaching this issue. Any substantive changes that require either legislative or expert panel input will take time to implement. In order to narrow the gap in the near term, we believe the following four requirements should be applied to Unapproved Animal Drugs nearly immediately:

- Products should be drug listed (NDC number).
- Facilities manufacturing these products should be registered (Federal facility registration).
- Products should be manufactured in an FDA inspected facility.
- Manufacturers should utilize USP/NF monograph materials and finished product monograph specifications whenever applicable.

Given the breadth and diversity of the products currently falling into this category of Unapproved Animal Drugs, a single solution seems impractical. Therefore, in addition to the above requirements, we believe a multi-faceted approach should be employed, based in part on intended use, risk, and target animal population.

GADA recommends two systems, differentiating between products that make disease claims and those that bear labeling limited to structure/function claims.

1. For products bearing labeling with structure/function claims, intended solely for use in companion (non food) animals, we believe that Canada has developed an Interim Notification Program<sup>2</sup> that is a sensible approach. In summary:

- Oral and topical products only.
- Structure/function claims only (no disease claims). Claims should be general and consistent for all products within a class.
- Mandatory Notification system - manufacturers identify details regarding the manufacturer, ingredients, label claims, etc. and attest to evidence of safety and effectiveness, cGMP compliance, and intention to report Adverse Drug Events.
- Individual notifications are confidential.
- System administrator accepts the product if requirements are met. (In Canada the system is administered by a third party, possibly in the US this function could be governed by the Office of Surveillance and Compliance).
- Accepted products and their labels are published.
- Only ingredients from an approved list can be used.

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<sup>2</sup> Health Canada, in cooperation with the Canadian Animal Health Institute, has developed a proposed Interim Notification Program for low-risk veterinary health products. More information is available at [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca).

A similar program in the United States would make significant progress toward providing a legitimate “home” for these products that pose lesser risk. In addition to the elements of the Canadian program listed above, GADA recommends, if a similar program were employed in the United States, that adverse event reporting would occur through the currently existing channels (Safety Reporting Portal, Form – 1932, etc.) and that manufacturers would complete a Quality Assurance Annual Product Review that would be maintained and available to the Agency upon request. The types of products we envision that would be eligible for this program may include: homeopathic preparations, botanicals, vitamins, minerals, algae, fungi, bacteria, probiotics and nutraceuticals. Consideration should also be given to allowing some products intended for food animal use to be included in this concept. Certain products, such as teat dips, moisturizers, emollients, coatings or shields, including iodine and some other antibacterial agents, though utilized on food animals, may lend themselves to this approach.

Products that are truly “grooming aides” that do not contain active ingredients and do not make drug claims are clearly outside the scope of this discussion, as these are not “Unapproved Animal Drugs;” rather they are, or should be, classified as cosmetics.

2. For products bearing disease claims, a system similar to the human OTC monograph system (though comprised of both OTC and Rx products) could be employed. This would establish claims, ingredients, etc. for certain products that anyone could then follow (as long as the firm is following GMPs, drug listing, etc.). Stakeholders could submit suggested products, labeling, supportive evidence, etc. to CVM, and a panel of experts would evaluate the submitted information in order to propose a monograph. This monograph could then be finalized by input from the regulated industry, or other due-process approach. Due to the complexity of establishing monographs, and the time investment required, monographs should be prioritized based on a number of factors. These factors could include: cumulative history/knowledge of the product in the marketplace, high volume products, medically necessary products, etc. Products with less historical knowledge base or novel concepts could be reserved for later.

In summary:

- All dosage forms would be eligible.
- Monographs would be established for both Rx and OTC products.
- Disease claims would be allowed.
- All classes of companion and food animal dosage forms would be eligible.
- The OTC and Rx Monograph Program could be administered/coordinated by OS&C.
- No submission of data for review would be required.
- Mandatory adherence to the established monographs.
- Products should be manufactured according to cGMP expectations, in an FDA registered and routinely inspected facility.

- Pharmacopoeia grade (USP / NF Monograph or others) active and inactive ingredients and finished product specifications should be required whenever applicable.
- Expert panels for each general class of products would confirm/write allowable general label claims and safety and precautionary warnings for each product class. Additionally, review of the acceptability of specific active ingredients would occur. The panels of experts could include Industry Stakeholders, AAVPT, practicing veterinarians, and academia.
- Report Adverse Drug Events through the established reporting channels.
- Manufacturer would complete a Quality Assurance Annual Product Review that would be maintained and available upon request.

A monograph system would require the development of “approved” label claims, likely through the use of advisory panels based on product category. It is not recommended, at this stage, to re-evaluate the current prescription versus OTC status of these products, rather to develop label claims in line with the current reality.

Regardless of the processes employed, any future structure for Unapproved Animal Drugs is useless without enforcement against those that are not compliant. Voluntary compliance is not enough. The current status of enforcement is lacking in protection for Sponsors who are compliant with the requirements for Approved Animal Drugs. There is general concern that this inadequate level of enforcement would persist and create an uneven playing field for those supplying products in a compliant manner. Therefore, if CVM implements new policies in regards to Unapproved Animal Drugs, there must also be an established and stringent approach to enforcing against those products and manufacturers that attempt to circumvent the systems that are developed as part of this initiative. Additionally, as the currently Unapproved Animal Drugs gain legitimate status, the expectation would be that enforcement against illegal pharmacy compounded drugs becomes easier.

There are some products currently within this category of Unapproved Animal Drugs that would lend themselves to full applications (either NADA or ANADA). This becomes more feasible if there are fewer hurdles to Sponsors as they approach the approval process. The ability to utilize (b)1 supplements to (b)2 applications, or the hybrid approval process, could lead to more approved animal drugs.

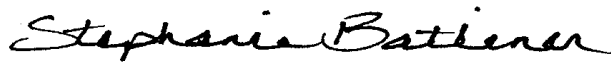
In addition, GADA would like to emphasize the value of legal, approved animal drugs, such as generic drugs approved by CVM through the ANADA process. Such drugs undergo a rigorous review by CVM to ensure safety, effectiveness, quality, and appropriate labeling. The goal of increasing the number of available legal animal drugs should also be met by increasing the number of animal drugs approved via the NADA and ANADA process. GADA applauds CVM’s efforts thus far to increase industry understanding of CVM’s requirements and to improve application review

times. To continue towards this goal of making more legal animal drugs available, especially approved animal drugs, it is paramount that CVM continue to work to improve efficiency of the approval process and continue its communication efforts with industry.

We recognize that the implementation of the proposals suggested here would require a significant amount of time. In the meantime, GADA supports the continued use of regulatory discretion when dealing with currently marketed Unapproved Animal Drugs. A slow, measured approach with lots of opportunity for industry feedback is warranted. Please also consider phased implementation of new initiatives and requirements, with future dates for compliance and enforcement. It is important to be cognizant of the necessity of these products to the animal health industry, and the animal welfare and economic hardship issues that could result from lack of access to these products.

We look forward to improvements that ensure continued availability of necessary animal drug therapies for animal owners and livestock producers, while ensuring that products that may risk animal safety or well-being are kept off the market. Access to animal drugs results in improved quality of life for companion animals and a safer food supply for human consumption.

Sincerely,



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