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Unapproved Animal Drugs

Industry Perspective by the Generic Animal Drug Alliance

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Background on GADA's Perspective:

- In December 2010, CVM/FDA requested creative approaches to addressing existing unapproved animal drugs (UADs) which are considered the "standard of care" and many are essential to protecting animal health
- FDA has historically exercised enforcement discretion for these UADs
- GADA represents companies which have an interest in the manufacturing and distribution of such products

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Initial Steps:

Because substantive changes will take time to implement, initially:

- Products should be drug listed (NDC number).
- Facilities should be registered with FDA.
- Products should be manufactured in an FDA-inspected facility.
- Manufacturers should use USP/NF monograph materials and finished product monograph specifications whenever applicable.

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Longer-Term: A Multi-Faceted Approach

- A multi-faceted approach can address the breadth of UADs:
  - One approach for products bearing labeling with **structure/function claims**;
  - A second approach for products with **disease claims**.

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A Multi-Faceted Approach: Structure & Function Claims

- Canada has implemented what may be a sensible model:
  - Health Canada and Canadian Animal Health Institute "Interim Notification Program" for low-risk veterinary health products.

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Structure & Function Claims

- Elements of the Interim Notification Program:
  - Oral and topical products only.
  - No disease claims.
  - Claims should be general and consistent for all products within a class.
  - Uses a Mandatory Notification system.
  - Individual notifications are confidential.

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Structure & Function Claims

- Elements of the Interim Notification Program (continued):
  - System administrator accepts the product if requirements are met.
  - Accepted products and their labels are published.
  - Only ingredients from an approved list can be used.
  - Adverse event reporting through existing channels.
  - Manufacturers complete a Quality Assurance Annual Product Review.

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A Multi-Faceted Approach: Disease Claims

- We suggest a CFR monograph system, comprised of both OTC and Rx products.
  - Would establish claims, ingredients, etc. for certain products that anyone could follow.
  - Stakeholders submit suggested products, labeling, supportive evidence, etc.
  - A panel of experts evaluates the submitted information and proposes a CFR monograph.
  - CFR monograph then finalized by input from the regulated industry, or other due-process approach.

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Disease Claims

- Under a CFR monograph system:
  - CFR monographs would be established for both Rx and OTC products.
  - All classes of companion and food animal dosage forms would be eligible.
  - The CFR monograph program should be administered /coordinated by CVM's OS&C.

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Disease Claims

- Under a CFR monograph system (continued):
  - Manufacturing according to cGMPs.
  - USP/NF Monograph or other active and inactive ingredients and finished product specifications required whenever applicable.
  - Mandatory adherence to the established CFR monographs.

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Disease Claims

- Under a CFR monograph system (continued):
  - Expert panels for each category of products should review active ingredients for safety and effectiveness and confirm/write allowable general label claims, safety and precautionary warnings.
  - The expert panels should include industry stakeholders, AAVPT, practicing veterinarians, and academia.

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Disease Claims:

A CFR monograph system would require the development of “approved” label claims, likely through the use of expert panels based on product category.

We are not recommending a re-evaluation of the current prescription vs. OTC status of these products; rather, we propose to develop label claims in line with the current and accepted industry practice.

In Summary:

- UADs need a legal home; GADA recommends a multi-faceted approach based on label claims.
- USP monographs should continue to serve an important role in defining standards.
- This legal framework will enable CVM to enforce against products that do not meet the criteria, such as illegally compounded drugs.

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Thank You!