North Carolina Department of Agriculture and Consumer Services, Veterinary Division
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On the current state of administration and dispensation of compounded veterinary drugs:

The issues surrounding this practice remain unresolved, given that the Food and Drug Administration (FDA) withdrew their draft of Guidance for Industry (GFI) #230, "Compounding Animal Drugs from Bulk Substances" in November 2017. At the time of this action, FDA stated that the agency did not plan to finalize the current draft, and intended to issue a new draft for public comment early this year.

Under current law, compounding of animal drugs from bulk drug substances is not permitted; however, the FDA recognizes there are circumstances where there is no approved drug that can be used or modified through compounding to treat a particular animal with a particular condition. In those limited situations, an animal drug compounded from bulk drug substances may be an appropriate treatment. Comments submitted to the docket related to GFI #230 supported that conclusion, and likely precipitated FDA's decision to develop and issue new guidance in its place rather than finalize the previous draft. In the new draft, FDA will consider the issues specific to compounding of animal drugs, including the significance of using compounded drugs as a treatment option for a variety of animal species and in various veterinary settings.

With the release of the new draft guidance, FDA will focus on the safety of compounded animal drugs. Additionally, the guidance will address FDA's intent to take action if the agency becomes aware of an animal or human safety concern associated with the use of an animal drug compounded from bulk drug substances. In the interim, veterinarians and other interested stakeholders are encouraged to contact FDA's Center for Veterinary Medicine with questions regarding the compounding of animal drugs.

For your reference, in this packet you will find documents germane to this issue which have been previously developed by the American Veterinary Medical Association (AVMA): the first document, from May 19, 2015, provides AVMA's original overview of FDA's draft of GFI #230, and a summary of the key information found therein. The second document, dated August 14, 2015, provides AVMA's overarching comments formally submitted to FDA on behalf of their members. These comments provide insight into the dilemmas created by the original draft language that could or would have affected the veterinary profession, and may well have contributed to FDA's decision to withdraw GFI #230 and issue completely new draft guidance for public comment. The third document, "Administration and Dispensing of Compounded Veterinary Drugs," was developed by the AVMA's State Advocacy Division, and contains a summary of state laws and regulations addressing the administration or dispensation of compounded drugs in a veterinarian's office or clinic. The fourth document contains a compilation and summary of North Carolina laws on compounding from AVMA's document "Statutes and Regulations Pertaining to Office Use and Dispensing of Compounding Preparations by Veterinarians."

Finally, please find the "Report of the Task Force on the Best Practices for Veterinary Compounding," developed by the National Association of Boards of Pharmacy (NABP). The task

force was established in response to Resolution 113-1-17, Best Practices for Veterinary Compounding, approved by NABP membership at the association's 113th annual meeting in May 2017. Included in their report was the Task Force Charge which provided the specific objectives to be addressed by the group:

1. Review existing state laws and regulations addressing compounding of animal (non-food-producing) products.
2. Review existing federal laws and regulations pertaining to the compounding of animal (non-food-producing) products.
3. Determine the applicable role of state boards of pharmacy in regulating the compounding of animal (non-food-producing) products and develop model regulations to amend the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) accordingly.

The report contains the task force's five internally-developed recommendations to address the resolution's charge.

Upon release of FDA's new draft of guidance regarding animal drug compounding, the NCDA&CS: Veterinary Division's team will provide an update on the status of this issue.