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October 15, 2020

Mr. Eric Nelson
Division of Compliance (HFV-230)
Center for Veterinary Medicine
c/o Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket #: FDA-2018-D-4533 CVM #256 – Compounding Animal Drugs from Bulk Drug Substances

Dear Mr. Nelson:

Thank you for the opportunity to comment on the FDA's draft guidance GFI#256, Compounding Animal Drugs from Bulk Drug Substances. These comments are on behalf of the Alaska State Veterinary Medical Association (AKVMA). AKVMA is comprised of 150 member veterinarians that represent the broad spectrum of veterinary medicine, including, but not limited to small animal, agriculture animals, exotic, wildlife, aquatic, equine practice, and those veterinarians working in research, academia, military, and other government capacities. The AKVMA is committed to helping protect the health, safety, and welfare of Alaskans, advocating for veterinarians to provide safe, competent professional veterinary services to consumers, and supporting scientifically based regulations that support these goals.

Veterinary practice encompasses a variety of patient species with sizes ranging from pocket pets who weigh just grams, to livestock that weighs in excess of 2,000 lbs. Veterinarians need to have access to effective medications that are affordable and readily obtained in a timely manner to treat their patients. Alaska veterinarians are working throughout the huge geographic area of Alaska, which presents unique challenges. For communities off of the road system, they rely on planes, barges, and ferries to get routine supplies and medications. Even in the bigger cities, our veterinarians require flexibility in the day-to-day practice, in order to meet the needs of their clients and patients.

When the FDA announced the proposed draft guidance for GFI #256 early in 2020, the AKVMA voiced our concerns directly to the FDA noting the deleterious impacts this guidance may have in veterinary patient care. At that time we noted our concerns about the guidance being a one size fits all product that appeared more applicable to human pharmacists and compounders, who deal with one species and have a plethora of approved products at their disposal to treat their patients.

For many practitioners this means we rely on compounding to produce either uniquely flavored or very small dosage preparations that will be accepted by often very selective patients. There is no feasible way for drug companies to produce FDA approved drugs to meet these needs (appropriate size, formulation, flavors) to include the wide variety of patient species we treat ranging from horses and livestock, to small animals like dogs, cats, and exotics such as iguanas, rabbits, rats, and snakes. For example, many exotic species need medications compounded into a form they will take (like a liquid) and in the proper dose for the size patient. Ciprofloxacin, for example, comes in a 500 mg tablet, but that can't be used in a parrot. Many exotic species hide their illnesses until they are quite sick—these patients need medications available quickly. AKVMA is concerned that extra paperwork would only delay their treatment and affect the success of treating them. As practitioners, it is imperative to have the flexibility to tailor our treatment plans to the diverse species. Although we see the need for FDA oversight to provide safe and effective drug preparations, veterinary compounding has filled a necessary void that will never be completely filled by FDA approved drugs.

Compounding has proven invaluable when there is a back order on a previously available FDA approved products. If bulk products are more restricted, as proposed, we fear patients will go untreated and suffer when approved ingredients are not available or are in short supply. We also have concerns about how compounding pharmacies access the approved base drugs. For example, some companies have been known to specifically restrict sales of approved base drugs to compounding pharmacies.

The AKVMA board has been in contact with representatives from the American Veterinary Medical Association (AVMA). Based on our discussions it appears we share the majority of the concerns and issues they have brought forward to the FDA:

- We agree that in general it should be considered "medically necessary" to compound a drug when the following criteria are met: the approved product is not commercially available, the needed compounded preparation cannot be made from the approved product, and/or and when there is no approved product from which to compound the needed preparation.
- We agree that all medications, including compounded drugs, need to be given within the context of a valid Veterinarian-Client-Patient-Relationship (VCPR) as defined by FDA.
- Veterinarians need to have access to office stock of compounded medications to treat more urgent and emergency situations. Some examples include unapproved substances for products used for humane euthanasia, depopulation and common poison antidotes.
- Because of our unique patients, veterinarians should be afforded some flexibility for compounded drugs, especially as it relates to non-food producing animals where little to no public risk is posed by their use.
- AKVMA opposes the use of an "approved list" of drugs for nonfood producing animals. Any such list would likely prove too limiting and would not encompass medications commonly used and otherwise commercially unavailable at this time. Each practitioner may have different needs based upon the array of patients they see.
- AKVMA opposes the requirement that the compounded medication produce a "clinical difference" in the patient for which the compounded medication is prescribed. The rationale for the use of the compounded medication, when noted in the medical record, should be sufficient documentation for use of that preparation. There are other potential reasons for using compounded preparations in nonfood-producing animals. These reasons may include reducing stress of administration to the patient or to enhance owner compliance and safety.
- AKVMA agrees the rationale for using a compounded medication be included in the medical record, as governed by the Alaska Board of Veterinary Examiners. However, we are strongly opposed to

placing such rationale on the prescription. Such requirements are not in place for other professions and this is not practical or reasonable in day to day practice.

The AKVMA also agrees that more collaboration and dialogue should occur between the FDA, veterinarians, and the veterinary pharmacists' industry. We believe engaging veterinarians can provide a proactive process which will assist in the formation of reasonable and useful guidance. It seems all too common, even in our own state, that pharmacy laws and regulations are decided by human health care providers without consideration or practical understanding of how they might impact veterinarians and their patients. Veterinarians are uniquely positioned to work within the One Health framework by protecting human and animal health, and also environmental health through the judicious use and disposal of the medications for which we are responsible. Providing veterinarians, the appropriate flexibility and discretion to treat animals with compounded medications, within certain parameters as described in this letter, will enhance our effectiveness to support One Health in the profession. We look forward to working alongside the FDA, drug companies, the AVMA, and veterinary pharmacies to help develop common sense guidance that works for all parties, but most importantly ensures that our patients can safely receive the medications they need to stay healthy.

Sincerely,

Dr. McKayla Dick, President AKVMA

"Promoting excellence and professionalism of Alaska Veterinarians in advancing the health and well-being of animals and the public."