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April 4, 2023



Director Tracey Forfa
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

Dear Director Forfa:

On behalf of the Alliance for Pharmacy Compounding, I write in response to a February 22, 2023 letter from Animal Health Institute (AHI) and Generic Animal Drug Alliance (GADA) to the Center for Veterinary Medicine regarding Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances – Guidance for Industry.

As you know, the Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

At a time when CVM and pharmacy compounding stakeholders have been working together in a cooperative and congenial manner on a guidance document that we all can live with, the accusations of AHI and GADA are unhelpful and misleading.

The U.S. animal drug compounding market value was estimated to be worth \$1.3 billion in 2022. Four of the 20+ pharmaceutical manufacturers that pay AHI to lobby on their behalf have seen an increase in revenue of 8+ percent in the past year, and report revenue of over \$15 billion. Clearly, animal drug compounding is not a threat to AHI member companies' market share, nor does it inhibit research and new product development, as all companies report robust R&D pipelines in their annual reports.

Likewise, since 2021, veterinary drug manufacturers have brought at least five drugs to market that were previously only available from compounding pharmacies. Those include K-Bro-Vet®, ThyroKare®, Zycosan®, Simplera® and Zorbium®.

In their letter, AHI and GADA assert that compounding pharmacies are intentionally copying their members' products with the intention of undermining the drug approval process and deprive the manufacturers of their profits. In fact, it is the manufacturers' inability to provide a reliable supply of veterinary medications – and the demand from veterinarians for medications for their patients – that prompts compounding pharmacies to fill the breach amid the frequent shortages that plague the veterinary drug industry.

To use Vetmedin® as an example, this life-saving medication has been on manufacturer's backorder numerous times since its approval in 2007. The most recent shortage of Vetmedin

began in February 2021 and lasted 16 months, finally resolving in June 2022. It was a time plagued by shortages of all kinds, and compounding pharmacies stepped up to fill the demand for essential animal medications when those animals' health was at risk.

For these reasons, we strongly object to the statements of AHI and GADA that compounders are making essentially a copy of commercially available drugs, particularly when many of these drugs are consistently experiencing shortages. We request that CVM continue to work with compounding industry stakeholders to ensure continued patient access.

Thank you for this opportunity to set the record straight. Please direct any questions to me at scott@a4pc.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Brunner', with a stylized, cursive script.

Scott Brunner, CAE
Chief Executive Officer