



February 3, 2020

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: FDA-2018-D-4533

To Whom It May Concern:

The undersigned organizations represent thousands of independent and compounding pharmacists, many who compound medications for veterinarians and their animal patients. We have heard concerns from our members and from other stakeholders about the potential negative impact that the recently released Draft Guidance for Industry (#256) “Compounding Animal Drugs from Bulk Substances” will have on access to and the quality of compounded medications in the treatment of animals. Our organizations will each be submitting substantive comments into the FDA docket on this guidance in the coming weeks.

Because GFI #256 was issued on November 20, 2019, just before the Thanksgiving and December holidays, many stakeholders are just learning of the guidance and seeking input from their constituencies. For this reason, and because we believe this draft will have a substantial impact on animal medicine that warrants robust public participation, we respectfully request that the comment period for GFI #256 be extended for 90 additional days to May 18, 2020.

Thank you in advance for your consideration of this request.

Sincerely,

American Pharmacists Association (APhA)

Alliance for Pharmacy Compounding (APC)

National Community Pharmacists Association (NCPA)