

Submitted electronically to: www.regulations.gov

June 30, 2025

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs From Bulk Drug Substances [[Docket No. FDA-2025-N-0082](#)]

To Whom It May Concern,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Food and Drug Administration's *Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs From Bulk Drug Substances [[Docket No. FDA-2025-N-0082](#)]*.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care (LTC) services and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members employ 205,000 individuals, and provide an expanding set of health care services to millions of patients every day. Our members are small business owners who are among America's most accessible health care providers.

FDA should rescind its 2023 *Guidance for Industry #256 (GFI 256)*. FDA seeks to regulate veterinary compounding, despite having no clear congressional mandate to do so. GFI 256 imposes broad restrictions on the use of bulk drug substances in veterinary compounding which undermine the clinical judgment of veterinarians and unnecessarily restricts access of compounded drugs for animals.

If FDA insists on maintaining GFI 256, a much more revised GFI 256 would be appropriate – one which: respects veterinary practice, prescribing veterinarians, and the essential role of compounded medications in animal health, and one which streamlines the bulk substance nomination process, incorporating transparency in its evaluations.

NCPA thanks the Food and Drug Administration for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal stroke extending to the right.

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association