

ISSUE BRIEF:

FDA Guidance for Industry (GFI) #256 – Compounding Animal Drugs from Bulk Drug Substances



On April 22, 2022, FDA’s Center for Veterinary Medicine (CVM) finalized the Guidance for Industry (GFI) #256 “Compounding Animal Drugs from Bulk Drug Substances – Guidance for Industry.”

The ability of many pharmacists to serve animal patients will be affected by this GFI. While there was a general lack of clarity in the new requirements that GFI #256 imposes on veterinarians and pharmacists, FDA’s Center for Veterinary Medicine in February 2023 responded to a July 26, 2022, letter from APC and NCPA requesting answers to more than 30 technical questions about GFI 256 compliance. It appears the agency took seriously our concerns about clarity in the GFI and has made a good-faith effort to describe its view of compliance. We urge state boards of pharmacy and regulatory agencies to review CVM’s responses and incorporate those principles into the state’s enforcement regime related to animal compounding.

Among the highlights of CVM’s answers to the associations’ questions:

- FDA does not intend to conduct inspections at 503B outsourcing facilities until it provides clarification on how GFI 256 applies to those facilities.
- FDA does not expect compounding pharmacies to confirm a valid veterinarian-client patient relationship (VCPR) exists.
- FDA will not question pharmacists’ professional judgment as to the documented reason a bulk ingredient was used instead of an FDA-approved drug.
- FDA does not expect compounders to retroactively obtain medical rationale for prescriptions written prior to April 1, 2023.
- CVM does not have a program to share with state licensing boards individual adverse events reports the agency receives.
- FDA generally intends to refrain from taking enforcement action for bulk drug substances that are currently under review so that veterinary access to those compounded products is not restricted during the review process

In a late January meeting with APC and NCPA leaders, CVM’s Dr. Bill Flynn stated that the agency’s previous announcement of an April 1, 2023, enforcement date for GFI 256 was not ironclad, and that the agency would instead begin phasing in enforcement. He added that any FY2023 inspections under the new guidance would be “informational” only.

APC has requested that the agency make a public statement to that effect, to assist compounders in coming into compliance and state boards of pharmacy in implementing enforcement standards.

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February 2023