

GFI256: Pharmacy Implications September 2022

A significant shift for veterinarians
may be only a few weeks away

Presenter



Speakers:

Daniel Rowan (Chief Commercial Officer)

Michael Blaire (Vice President - Government and Regulatory Affairs)



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Agenda

- A brief review of GFI256
- Components of GFI256
- Potential ramifications to compounding pharmacies

#256

**Compounding Animal Drugs from Bulk
Drug Substances**

Guidance for Industry

This version of the guidance replaces the version made available April 14, 2022. This revision makes a clarification to footnote 21 on page 6.

Submit comments on this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-4533.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <https://www.fda.gov/animal-venterinary>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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The information collection provisions in Section III of this guidance, which are footnoted with an asterisk for easy identification, are under OMB review and are not for current implementation. See additional FRA statement in Section IV of this guidance.



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Brief Timeline of GFI 256

- AMDUCA – the Animal Medicinal Drug Use Clarification Act (1994)
- Compliance Policy Guide (CPG) 608.400 – Compounding of Drugs for use in Animals (1996,2003)
- GFI 230 – Compounding Animal Drugs From Bulk Drug Substances (2015)
 - Significantly broader restrictions.
 - Compounding and veterinary industries partnered to push back. FDA withdrew in 2017.



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Brief Timeline of GFI 256..cont...

- GFI 256: Compounding Animal Drugs From Bulk Drug Substances
 - “Balances FDA’s concerns about the safety, effectiveness, and quality of animal drugs compounded from bulk drug substances...with the need for such drugs...”
 - FDA introduces draft GFI 256 November, 2019, publishes final April, 2022.
 - FDA received >2,000 comments
 - Written in more understandable language
 - Provides examples
 - Made the nomination process more workable
 - Allow medications “under review” to be dispensed for office use



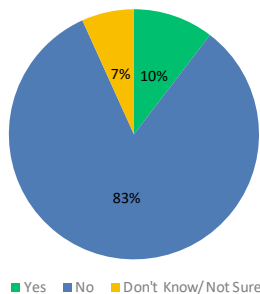
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Industry Awareness

Recent national surveys show staggeringly high percentage of those who are unaware of GFI 256, and the readiness it requires:

Veterinary Community:

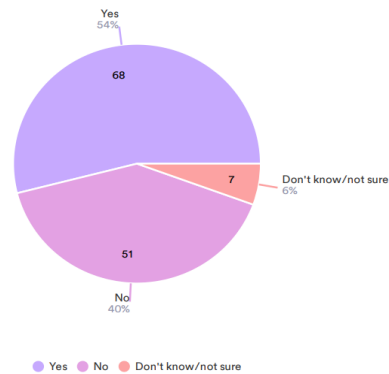
**Before today, were you aware that this GFI has been finalized?*



* Survey conducted by Wedgewood Pharmacy; results reflect feedback of approx. 1500 respondents

Pharmacists:

** Before today, were you aware that GFI #256, regarding animal compounding, has been finalized?*



*Survey conducted by APC; results reflect feedback of approx. 126 respondents

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New Elements and Potential Impact

- **Justification for use of bulk drug substances**
 - Absence of justification will require compounding from FDA approved drugs and not API
 - Patient care risks due to allergens, toxins, etc.
- **Nominations of medications available for office use – the “lists”**
 - Nominations require time and effort for research, including API, dosage form(s), strength(s), species, and indication.
 - List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals
 - List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species
 - Bulk Drug Substances Currently Under Review
 - Bulk Drug Substances Reviewed and Not Listed
 - Dependent on a yet unknown FDA review process
 - Monitoring of “lists” and ongoing changes to availability

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New Elements and Potential Impact..cont..

- **Adverse event reporting using FDA Form 1932a**
 - Burdensome form - estimates of 1 hour to complete
- **Labeling requirements for office use medications and prescriptions**
 - Additional packaging for both office use and prescriptions
 - Office use medications labeled with indication and other nomination data
- **Changes will be required to SOPs and workflow**
- ****Medical rationale required to be provided by veterinarian and documented with prescription**
 - Increased friction during intake and longer talk time for RPh both on and offline



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****List of medical rationale developed by Wedgewood Pharmacy** *(may require technology changes or updates)*

- Dosing animal with an approved product would reduce compliance and/or is not practical to achieve medical outcome.
 - Example: multiple tablets/capsules or high-volume ML needed to dose animal
 - Example: Patient cannot be dosed orally, requires a topical dosage form
- Patient requires dose that is unachievable or unsafe with commercially available product
 - Example: pet cannot safely be dosed with approved dosage form
 - Example: Medications cannot be split appropriately (fraction of dose is unachievable)
- FDA approved product unavailable
 - Example: Backorder/shortage
 - Example: Cisapride not available commercially
- Patient has a sensitivity or intolerance to an inactive ingredient in the commercially available product and/or requires medically necessary avoidance
- Medication combination/strengths/dosage forms are not available as an approved product
 - Example: Otic Ear combinations not available commercially
 - Example: Combination medications for one dose, enhances compliance/safety
- Patient has an allergy to inactive ingredient in commercially approved product (must provide allergy)
 - Example: Hypersensitivity to approved product inactive ingredients
 - Example: Protein allergies
- An inactive ingredient in approved commercial product is toxic to species or environment/inhabitants surrounding it.
- Chemical properties of the FDA-approved drug(s) prevent practical and effective use in the compounding of a specific drug.
 - Example: Creating a sterile ophthalmic solution form from a topical dosage form
 - Example: Creating a sterile injectable from a non-sterile dosage form



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Take Action Now

- **Nominations of medications available for office use – the “lists”**
 - Review current nominations at <https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals>
 - Dozens of nominations have been submitted to date: Submit your own.
- **Request for an extension**
 - Several organizations, including APC, OFA and four members of congress have submitted requests for delayed enforcement implementation.
 - Submit your own letter. APC can provide guidance on the structure of a formal letter.
- **Prepare your pharmacy; create a checklist for operational changes**
- **Create awareness of the October 1, 2022, enforcement date with your veterinary customers**



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Q&A and Closing Remarks



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Thank you!

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Scott Brunner, CAE

scott@a4pc.org



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