AVMA Feedback on FDA's Draft GFI #256

September 2, 2020

FDA draft GFI #256, *Compounding Animal Drugs from Bulk Drug Substances*

- Compounded animal drugs do not undergo review by the FDA.
- FDA acknowledges that an animal drug compounded from bulk drug substances may be a medically necessary where there is no medically appropriate FDA-approved drug.
- FDA has developed this draft guidance to explain when the Agency does not intend to take enforcement action for violations of the federal Food Drug &Cosmetic Act's requirements drug approval.

Draft GFI #256 provisions address—

- Filling patient-specific prescriptions for nonfood-producing animals;
- Compounding "office stock" from bulk drug substances for nonfood-producing animals; and
- Compounding antidotes for food-producing animals.

AVMA Supports—

Three general sets of circumstances in which compounding from bulk drug substances may be medically necessary:

- The approved product is not commercially available,
- The needed compounded preparation cannot be made from the approved product, or
- There is no approved product from which to compound the needed preparation.

AVMA Supports—

- Requirement that a VCPR as defined by FDA must exist for use of a compounded preparation in an animal patient.
- The veterinarian's ability to maintain sufficient quantities of compounded preparations in their office for urgent administration or dispensing in emergency situations.
- Requirement that compounding occur under the direct supervision of the veterinarian or pharmacist and that, in the case of a pharmacist, such compounding occur in a state-licensed pharmacy or federal facility.

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AVMA Supports—

- Requirement that the entity compounding the drug determine and document the reason(s) why the FDA-approved drug cannot be used as the source of the active ingredient.
- The dispensing of the drug directly from the pharmacist to the veterinarian or owner/caretaker; or by the veterinarian to the owner/caretaker of an animal patient or to another veterinarian in the same practice/physical location, but is otherwise not dispensed or transferred by the pharmacy, pharmacist, or veterinarian to a third party (e.g., distributor, retailer, or veterinarian in another practice).

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AVMA Supports—

- Proper labeling of all dispensed prescription medications, including requirements set forth in this guidance.

Note:

- AVMA is asking for further collaboration on developing and strengthening the adverse event reporting system.
- AVMA wants FDA to engage in dialogue with veterinarians and pharmacists about the appropriate system and method to be used for reporting adverse events associated with compounded products.
- AVMA has concerns about the proposed use of Form FDA 1932a.

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AVMA Supports—

With conditions, requirements that the drug be compounded in accordance with the current United States Pharmacopeia and National Formulary (USP-NF) Chapters <795> "Pharmaceutical Compounding – Nonsterile Preparations" or <797> "Pharmaceutical Compounding-Sterile Preparations" and in compliance with the standards of all applicable USP-NF monographs (e.g., a monograph for a bulk drug substance or a monograph for a compounded finished product).

- **AVMA asking FDA to update GFI # 256, or any successors, at such time as other relevant USP chapters become available.**

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Section III.A.

Patient-Specific Prescriptions for Nonfood-Producing Animals

- No copies
- Strike reference to “clinical difference”
- Strike requirement to document medical rationale on prescription

Section III.B.

"Office Stock" for Nonfood-Producing Animals

- AVMA opposes the use of a list for substances to be used as office stock drugs in nonfood-producing animals.
- We recommend using criteria listed in the Appendix:
  - There is no commercially available FDA-approved, conditionally approved, or indexed animal drug that can be used as labeled to treat the condition;
  - There is no commercially available FDA-approved animal or human drug that could be used in an extra label manner under section 512(a)(4) or (a)(5) of the FD&C Act and 21 CFR part 530 to treat the condition;
  - The drug cannot be compounded from a commercially available FDA-approved animal or human drug consistent with 21 CFR part 530;
  - Immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
  - FDA has not identified a significant safety concern specific to use of the bulk drug substance in animals.

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Section III.C.

Compounding Drugs for Use as Antidotes for Food-Producing Animals

- AVMA supports a list of bulk drug substances for compounding office stock drugs for poison antidotes for food-producing animals, but must add substances used to compound drugs used for depopulation and euthanasia.
  - AVMA requests that the active ingredients for those drugs in the AVMA's euthanasia and depopulation guidelines for which an FDA-approved, conditionally approved, or indexed drug is not available be added or incorporated by reference into the list for use in food-producing animals.

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Published on November 2019.

Comments due October 15, 2020.

To electronically submit comments to the docket, visit www.regulations.gov and type FDA-2018-D-4533 in the search box.

Resources

AVMA policies on compounding

- Veterinary Compounding

https://www.avma.org/KB/Policies/Pages/Compounding.aspx

- Compounding from Unapproved (Bulk) Substances in Non-Food Animals

https://www.avma.org/KB/Policies/Pages/Compounding-from-Unapproved-Bulk-Substances-in-Non-Food-Animals.aspx

- Compounding from Unapproved (Bulk) Substances in Food Animals

https://www.avma.org/KB/Policies/Pages/Compounding-from-Unapproved-Bulk-Substances-in-Food-Animals.aspx

FDA draft GFI #256

- FDA guidance materials: https://www.fda.gov/animal-veterinary/cvm-updates/fda-releases-revised-draft-guidance-compounding-animal-drugs-bulk-drug-substances
- FDA Q&A: https://www.fda.gov/animal-veterinary/animal-drug-compounding/qa-draft-gfi-256-compounding-animal-drugs-bulk-drug-substances