Alliance for Pharmacy Compounding
Compounding the Joy of Living

ISSUE BRIEF SEPTEMBER, 2024

FDA's Center for Veterinary Medicine is tightening the noose on animal drug compounding from bulk substances

Until recently, veterinarians kept a variety of compounded medications in stock for office use which allowed them to begin treatment immediately and reduce animal suffering. These medications also allowed veterinarians to have access to appropriate dosage forms or flavors that could be critical for driving patient and pet owner compliance. Recent action by the FDA is jeopardizing care and may result in additional patient harm.

FDA Guidance for Industry #256

- In April 2023, FDA's Guidance for Industry #256 (GFI#256) became effective.
- GFI #256 places new restrictions on compounding medications from bulk drug substances for office stock by dividing these medications among listed, not-listed, and under-review lists.
- Compounding pharmacies are only permitted to sell for office stock those drugs which are either on the "listed" or "under review" lists.
- To date, FDA has rejected 93% of the dosage forms and strengths of drugs that have been nominated. FDA's rejection essentially substitutes their medical judgment for that of the veterinarian and makes it non-compliant for pharmacies to sell to veterinarians as office stock many drugs that veterinarians have used as office stock for decades.
- If standard-of-care drugs are not able to be stocked in veterinarian's offices, pets and animals will be harmed.

- **503B Outsourcing Facilities**
  - FDA has recently announced that it is working on draft Guidance for Industry #256B (GFI #256B), for 503B outsourcing facilities.
  - While this guidance has not yet been published, the "listed, not-listed and under-review lists" procedure should not apply to animal drugs produced at 503Bs because 503Bs are not permitted to sell patient-specific drugs. If the principals of GFI #256 are applied to 503Bs, it is likely to eliminate the production of animal drugs in a 503B, further compromising access.

- **Inspections and "Untitled Letters"**
  - FDA is issuing and publishing "Untitled Letters" that are sent to compounding pharmacies following an inspection. The issues cited in the letters are not brought up during the inspection, discussed in the closeout session, or noted on a Form 483.
  - FDA threatens that failure to correct the issues noted in the untitled letter will cause the pharmacy to be inspected under cGMP.

What are we asking?

We're asking members of Congress to contact FDA's Center for Veterinary Medicine to express concerns about these restrictions – including the slowness in developing a robust set of "listed" drugs and the arbitrary nature of drugs they decline to add to the list. Specifically, ask CVM to:

- Place on the "listed list" nine critical drugs that veterinarians say are needed for office stock.
- Reduce the administrative burdens FDA has placed on veterinarians and pharmacies through it's GFI #256 Question and Answer documents.
- Ensure that GFI #256B does not apply the listing review and decision process of GFI #256 to 503B facilities.
- Maintain transparency with pharmacies during the inspection process and to adhere to broad interpretation of GFI#256 guidelines rather than a severely restricted one that will result in reduced access to medications and increased patient suffering.

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