

Why Forcing Compounding Pharmacies to Compound from Finished Pharmaceutical Goods Instead of Bulk Active Pharmaceutical Ingredients Will Cause a Dramatic Increase in the Cost of Vital Compounded Medications.

FDA's new Draft Guidance for Industry, [Compounding Animal Drugs from Bulk Drug Substances](#), would virtually eliminate this scientific best practice and force compounders to make custom pet medications from finished pills, tablets, capsules, and vials purchased from pharmaceutical companies—if they can obtain them. This will increase costs by an average 300%, decrease quality, increase risk, and dramatically reduce the availability of compounded medications that are regularly prescribed and prepared by 99% of veterinarians. The result: unnecessary animal suffering and death.

FDA's new Draft Guidance for Industry, [Compounding Animal Drugs from Bulk Drug Substances](#) would force compounding pharmacies to work with finished products rather than bulk active pharmaceutical ingredients (APIs). FDA offers no evidence whatsoever that using FDA-approved products as starting materials for preparing compounded medications offers better quality or safety over using bulk ingredients, which are required to be purchased from FDA-regulated and inspected facilities. (See [Why Compounding Pharmacies Use Bulk Active Pharmaceutical Ingredients from FDA Registered Suppliers to Make Custom Medications—and Why That's Best.](#))

Yet this new guidance could limit the number of bulk ingredients pharmacies could use to *just seven*.¹ That compares with the more than 450+ bulk ingredients that represent the current standard of care in animal health. This requirement, should it be finalized, would cause a dramatic increase in the cost of compounded medications, which 99% of veterinarians say are important to their practices and patients.

Costs will increase from 50% - 3,000%.

One compounding pharmacy conducted an analysis of the eight most-frequently prescribed compounded medications for pets made from bulk APIs, representing about 45% of all prescriptions filled by the pharmacy. The results were stunning. If that pharmacy were required to make those prescriptions from finished tablets, capsules, or vials of liquid, the cost would increase *between 50% and 3,000%*. The *average* increase in cost was 300%. [Here is a list of examples.](#)

But it's not just the cost of finished pharmaceutical products versus bulk APIs that increase:

Labor costs increase.

Someone must open the shipping containers, bags, boxes, bottles, or vials in which the finished goods arrive. Then the tablets or capsules must be crushed or opened. Since the material has fillers and binders in it, it has to be "worked" longer, sent through secondary processing, or have other ingredients added to make it smooth and workable. In the case of sterile medications that arrive in tiny vials, the contents would have to be extracted from each vial individually. None of these steps are necessary when bulk APIs are used. Labor costs alone would increase by 30% to 40%.

Waste increases.

The waste generated by compounding using finished pharmaceutical goods instead of bulk APIs track the reasons that labor costs increases: wasted active ingredients, wasted packaging, and wasted time. Because compounding is custom and often prescriptions are prepared for just one patient, any content not used from a finished good in making a compound would be discarded.

¹ FDA proposed a bulk-ingredient positive list nomination process for office use compounding. However, almost none of the most commonly compounded active pharmaceutical ingredients will clear FDA's established hurdles.

Product size, packaging, and shipping costs increase.

By adding ingredients to account for problems associated with using finished pharmaceutical goods for compounding, the size of medications themselves will increase. The physical size of a dose of medication often is a key factor in a pet owner's ability to give and to a pet's willingness to take a medication. (And a major reason why compounding pharmacies exist!) Starting with commercially manufactured finished goods is especially problematic in instances where higher concentrations are required to reduce the volume of medication needing to be administered to a patient. This includes preparing a smaller-volume dose for administration to a difficult-to-treat feline patient or needing to significantly increase the dose for an equine patient, without requiring massive amounts of excipients to be included with each dose. Starting with finished goods removes the kind of flexibility that veterinarians and pharmacies need to ensure compliance with medication regimens. As far as cost is concerned, it simply costs more to package bigger individual medications, in bigger bottles, vials, and shipping containers, which weigh more and cost more to ship. (Packaging and shipping costs are not included in the 300% average cost increase.)

In a [recent nationwide study of veterinarians](#) one veterinarian noted,

"I have never been shown a good reason to control the use of bulk ingredients in the compounding of veterinary medications other than to protect the pharmaceutical companies that make the commercially available medications. However, I have many reasons to believe that the use of bulk ingredients by a compounding pharmacy to supply my clients and patients with the formulations in the correct dosage form and size is very important to my ability to safely care for my patients and their owners."

That veterinarian is right.

Examples

Price Increase Examples Bulk API vs FDA Approved Drugs

Drug	Species	Indication	Price of compounded medication with Bulk API	Price of compounded medication with FDA approved Drug	% change	Strength/ Dosage Form	Size
Penicillamine	Dog	Copper storage-associated hepatopathies (chelator/antidote)	\$76.00	\$15,080.00	19742%	300mg Capsules	60ct
Phenoxybenzamine	Dog/Cat	Functional urethral obstruction	\$51.00	\$2,700.00	5194%	2.5mg Capsules	100ct
Isoxsuprine	Horse	Navicular disease	\$77.00	\$1,900.00	2368%	500mg/scoop Oral Powder	60 Scoops
Cyproheptadine	Horse	Head shaking & PPID (aka Cushing's disease)	\$68.00	\$740.00	988%	150mg/scoop Oral Powder	100 Scoops
Doxycycline	Horse	Lyme disease	\$120.00	\$1,075.00	796%	5gm/scoop Oral Powder	60 Scoops
Hydroxyzine	Horse	Allergies	\$46.00	\$235.00	411%	500mg/scoop Oral Powder	100 Scoops
Prazosin	Cat	Functional urethral obstruction	\$38.00	\$150.00	295%	0.5mg Tablets	100ct
Fludrocortisone	Dog	Hypoadrenocorticism	\$54.50	\$190.00	249%	0.2mg Capsules	100ct
Itraconazole	Dog	Systemic fungal infections	\$58.00	\$150.00	159%	200mg Capsules	30ct
Budesonide	Dog/Cat	IBD	\$63.50	\$115.00	81%	1mg Tablets	120ct

Chemotherapy:

Lomustine*	Dog	Cancers	\$40.80	\$743.07	1721%	60mg Capsules	1ct
Chlorambucil	Dog	Cancers	\$41.95	\$389.00	827%	1mg Capsules	15ct
Melphalan	Dog	Cancers	\$78.25	\$160.00	104%	0.5mg Capsules	30ct

*Manufacturer will not sell to compounders