Provision	Section 503A	GFI #256
Available exemptions, if conditions are met	Drugs compounded in accordance with all conditions of section 503A are exempt from: • Section 501(a)(2)(B) (current good manufacturing practice requirements), • Section 502(f)(1) (labeling with adequate directions for use), and • Section 505 (new drug approval requirements).	Section 503A exemptions for compounded human drugs do not apply to drugs compounded for use in animals.
Types of compounder(s)	Compounding is by a: • Licensed pharmacist in a state-licensed pharmacy or federal facility, or a • Licensed physician.	Compounding is by or under the direct supervision of a: • veterinarian, or • a pharmacist in a State-licensed pharmacy or Federal facility.
Patient-specific prescriptions	Compounding must be based on the receipt of a valid prescription for an identified individual patient. It can occur after the receipt of the prescription, or in limited quantities before the receipt of such a prescription.	Compounding for nonfood-producing animals may be done on a valid patient-specific prescription; or without a patient-specific prescription for "office stock." When compounding antidotes for food-producing animals, or sedatives or anesthetics for free-range wildlife species, there is no requirement for a patient-specific prescription. However, the circumstances are such that it may be used by or on the order of a licensed veterinarian that has a valid veterinarian-client-patient relationship.
Bulk drug substances	Bulk drug substance must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with FDA under section 510. In addition, the bulk drug substance must comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if one exists, and the USP chapter on pharmacy compounding; if an applicable USP/NF monograph does not exist, be a component of an FDA-approved drug; or if such a monograph does not exist and the substance is not a component of an FDA-approved drug, appear on a list of bulk drug substances that can be used in compounding under section 503A developed by FDA through regulations. See also, FDA's final guidance describing its interim policy for compounders using bulk drug substances while the list of bulk drug substances is being developed.	For patient-specific compounding, all bulk drug substances, inactive ingredients, and finished drug products used in compounding meet the standards set in any applicable USP/NF monograph and comply with other FD&C Act requirements for drug components. When compounding for office stock intended for use in a nonfood-producing animals, the drug must be compounded from a bulk drug substance listed on FDA's "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals" and all bulk drug substances, inactive ingredients, and finished drug products used in compounding meet the standards set in any applicable USP-NF monograph and comply with other FD&C Act requirements for drug components. When compounding for use as antidotes for food-producing animals or sedatives/anesthetics for free-range wildlife species, the drug is compounded from a bulk drug substance on the "List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species."
Drugs presenting demonstrable difficulties for compounding	The drug is not identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.	No similar provision for compounding animal drugs.
Drugs that are essentially copies	The drug is compounded by a licensed pharmacist or licensed physician that does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product.	When compounding pursuant to a patient-specific prescription, the compounded drug is not a copy of a marketed FDA-approved or indexed drug. Or, if it is a copy, there is a difference between the compounded drug and FDA-approved or indexed drug that will produce a clinical difference in the identified patient as determined by the treating veterinarian. See GFI #256, p.11, outlining FDA's position on when a drug compounded from bulk for a nonfood-producing animal is a copy.
Wholesaling	No explicit condition in section 503A but other requirements of the FD&C Act may apply.	The enforcement discretion policy described in GFI#256 does not apply to compounded drugs that are dispensed or transferred to a third party such as a distributor or retailer, or by a pharmacy to a veterinarian who did not write the prescription.
Adverse event reporting	No explicit condition in section 503A.	Upon becoming aware of any adverse event or product defect, the pharmacist or veterinarian who compounded the drug reports the event on Form FDA 1932a within 15 business days.
	Source: FD&C Act Provisions that Apply to Human Drug Compounding	**Source:** GFI #256