

FDA's GFI #256

Medical Rationales

As of 4/1/2023, you may be required to include one of the following medical rationales with new prescriptions for compounded medications:

Commercial product would reduce compliance and/or is not effective for achieving medical outcome.

Examples:

- *Multiple tablets/capsules or high volume ML needed to dose animal*
- *Patient cannot be dosed orally, requires a topical dosage form*
- *Medications cannot be split appropriately (fraction of dose is unachievable)*
- *Combination medications for one dose, enhances compliance/safety*

Commercial product is not available and/or unable to source.

Examples:

- *Backorder/shortage*
- *Cisapride not readily available commercially*
- *Otic Ear combinations not available commercially*

Utilization of commercially available dosage form is unachievable or unsafe for patient.

Examples:

- *Creating a sterile ophthalmic solution form from a topical dosage form*
- *Creating a sterile injectable from a non-sterile dosage form*
- *Pet cannot safely be dosed with approved dosage form*

Patient and/or population has an intolerance, sensitivity, toxicity, or aversion to commercial product.

Examples:

- *Patient has severe GI upset with oral route, topical preferred*
- *Lactose intolerance*
- *Xylitol toxicity*