

**From:** General Board of Pharmacy Subscriber List [<mailto:PHARM-GENERAL@DCALISTS.CA.GOV>] **On Behalf Of** California State Board of Pharmacy  
**Sent:** Friday, January 11, 2019 3:59 PM  
**To:** [PHARM-GENERAL@DCALISTS.CA.GOV](mailto:PHARM-GENERAL@DCALISTS.CA.GOV)  
**Subject:** Compounding Safety Alert

It has come to the attention of the California State Board of Pharmacy that sterile compounded drug preparations have recently been prepared with a dietary supplement grade ingredient which is NOT intended for use in such preparations. In addition, a sterile compounded preparation that included a currently available dietary supplement of L-Glutathione Reduced, when tested, revealed an endotoxin level 2.5 times higher than the acceptable limit. (California Code Regulations, title 16 (CCR), section 1751.7.) This resulted in at least six cases of consumer harm.

In accordance with its consumer protection mandate, the board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required. (CCR section 1735.8.)

Please note that the label may say that the ingredient may be used for “pharmaceutical compounding,” but the caution, indicating “dietary supplement” reflects that the ingredient is only appropriate for compounding OTC products.

Dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as 10 times more impurities when compared to pharmaceutical grade standards appropriate for compounding. These impurities can cause patient harm. The pharmacist performing or supervising the compounding has the responsibility to ensure all chemicals, bulk drug substances, drug products, and other components used to make compounding drug preparations are of the appropriate integrity, potency, quality. (CCR section 1735.2.)