

# Letco Medical Considers Patient Safety Its Highest Priority And Supports The FDA's Warning Concerning The Inappropriate Use Of Glutathione Powder In Compounded Sterile Injectable Formulations



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**Letco Medical** →

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WAYNE, Pa., Feb. 1, 2019 /PRNewswire/ -- On February 1, 2019, the Federal Food and Drug Administration (FDA) issued a public statement warning compounders "not to use glutathione-L-reduced powder distributed by Letco Medical, Decatur, Alabama, to compound sterile injectable drugs for patients." Letco Medical considers patient safety its highest priority, and thus it welcomes the FDA's warning concerning the improper use of dietary supplement-labeled ingredients, such as L-glutathione by compounders in sterile formulations. L-glutathione and all dietary supplement grade ingredients Letco Medical sells are clearly labeled with the statement "Caution: Dietary Supplement." When used as indicated on the label per 21 U.S.C. § 321, dietary supplements sold by Letco Medical are safe.

We were informed of, and believe that the FDA's statement is a result of a case where a compounding pharmacy improperly utilized Letco Medical's dietary supplement-grade L-glutathione ingredient in a sterile injectable drug product contrary to its labeled use and released and dispensed the compounded drug product without testing it. As all compounding professionals are aware, compounding ingredients labeled "Caution: Dietary Supplement" are not suitable to produce sterile drug products under any circumstances – regardless of manufacturer, supplier or lot number. We would like to take this opportunity to reiterate this requirement to the marketplace.

If you have questions or concerns about the proper use of dietary supplements or Letco's product labels, please contact us at 877-538-2679.

### **About Letco Medical, L.L.C.**

Letco Medical, L.L.C. ("Letco Med"), a 100% employee-owned company headquartered in Wayne, PA, is the supply partner of choice for profit-conscious compounding pharmacies everywhere. Letco Med has invested heavily in building a company that can serve the needs of compounding pharmacists today, tomorrow and into the future, with a full line of products and complementary programs and services. With a dedicated focus on the U.S. compounding market, Letco Med provides a wide and comprehensive portfolio of safe and consistent top-quality chemicals, compounding supplies and equipment at highly competitive prices. Letco Med's product line includes chemicals covering a broad range of therapeutic categories, as well as supplies, equipment, capsules, pre-made topical bases and oral delivery vehicles. In addition, Letco Med carries a deep assortment of dosage forms and delivery systems.

Since its inception in 1993, Letco Med has earned and built a reputation as one of the most innovative companies in the compounding industry. Letco Med is focused on unwavering quality, exemplified by the company's industry-leading quality assurance programs and stringent quality control procedures.

For more information, visit [www.letcomed.com](http://www.letcomed.com).

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