



QUALITY ALERT NOTICE II: SERMORELIN

October 11, 2018

Dear Valued Customer,

This quality alert is a follow-up notification to the original alert Letco issued on May 9, 2018 regarding Sermorelin. We have received very recent reports of inferior, low-quality Sermorelin in the marketplace that we consider to be a threat to our customers, their patients and the integrity of compounding. Please be advised that products offered at bargain basement prices, often come with not only lower quality, but at a higher risk to you and your patients.

If you are concerned about the quality of your Sermorelin, and the safety of your patients, you should be asking your supplier where they sourced the product they are offering you.

ATTRIBUTE	LETCO SOURCE	OTHER SUPPLIERS
Factory Location	Nanjing, Jiangsu Province, China	Chengdu, Sichuan Province, China
Passed FDA inspection	Yes	No
Follows ICH Q7A guidelines	Yes	No
Has a valid cGMP certification	Yes	No
Has an electronic quality management system	Yes	No
Has an Out of Spec procedure in place	Yes	No
Provides employees with general GMP training	Yes	No
Verifies potency of each receipt with an FDA-registered and Letco-audited third-party laboratory	Yes	No
Has robust procedures to control all aspects of manufacturing, holding and laboratory activities	Yes	No

One of the most critical aspects of Letco’s quality assurance program and unblemished FDA record is our obligation and commitment to ensure the manufacturers we source products from meet our customers’ needs in terms of safety, identity, strength, quality, and purity. When you purchase from Letco, you have the knowledge and confidence that we sourced our products from a manufacturer whose API product was thoroughly examined, tested and proven to meet and/or exceed standards for proposed use.

We believe the decision on who to buy your product from is an easy one; not just with Sermorelin, but for all of your product purchases.

We are Letco – Let Us Help.