

Lonestar Research
2028 E Ben White Blvd #240
Austin, TX 78741

lab@lonestarlaboratory.org
(512) 222-8436

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To Whom It May Concern,

This letter serves as a formal statement of materials compliance for all peptides and raw materials supplied and distributed by Lonestar Research. Lonestar Research is committed to ensuring that all materials meet applicable state and federal regulatory requirements, including but not limited to:

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.)
- FDA Research Use Only (RUO) Labeling & Distribution Requirements (21 C.F.R. § 809.10(c))
- Prohibited Acts & Misbranding (21 U.S.C. § 331 & 352)
- Texas Dangerous Drug Act (Texas Health & Safety Code § 483.001 et seq.)
- Texas Food, Drug, and Cosmetic Act (Texas Health & Safety Code § 431.001 et seq.)
- Texas Controlled Substances Act (Texas Health & Safety Code § 481.001 et seq.)

Supplier Compliance & Certification

All vendors supplying peptides and raw materials to Lonestar Research are required to sign a Supplier Agreement mandating compliance with federal and state regulations. This agreement ensures that:

- All supplied materials are certified as Research Use Only (RUO) under 21 C.F.R. § 809.10(c) and are not subject to FDA drug approval requirements under 21 U.S.C. § 301 et seq.
- Materials are not classified as drugs, medications, or pharmaceuticals under 21 U.S.C. § 321(g)(1) or Texas Health & Safety Code § 483.001 et seq.
- No controlled substances are included in any supplied materials as defined by Texas Health & Safety Code § 481.001 et seq.
- Proper labeling is maintained on all shipments, including clear markings of "FOR RESEARCH USE ONLY – NOT FOR HUMAN OR VETERINARY USE."
- Certificates of Analysis (COAs) and batch-specific purity reports are provided for each shipment, verifying that purity levels meet or exceed 98% as determined by third-party testing.

Quality Control & Testing Protocols

Lonestar Research implements a strict quality control program to verify the purity, safety, and compliance of all peptides and raw materials before distribution. Our testing procedures include:

- High-Performance Liquid Chromatography (HPLC) and Mass Spectrometry (MS) testing conducted on at least 2% of each shipment to confirm purity and composition.
- Batch records and testing documentation are reviewed prior to any product release to ensure compliance with FDA RUO labeling standards and Texas DSHS regulations.
- All testing records are maintained for a minimum of five (5) years for regulatory traceability.

Regulatory Monitoring & Compliance Updates

Lonestar Research continuously monitors federal and state regulatory changes to maintain compliance. This includes:

- FDA regulatory tracking, including updates to 21 C.F.R. § 809.10(c) and FDA guidance on RUO materials.
- Monitoring of Texas Department of State Health Services (DSHS) regulations for any amendments to Texas Health & Safety Code §§ 431, 481, and 483.
- Legal and regulatory review by compliance consultants to ensure adherence to new laws or regulatory actions impacting RUO materials.

Identified Vendors & Roles

Lonestar Research maintains confidential vendor relationships; however, all suppliers are required to meet the following roles for compliance:

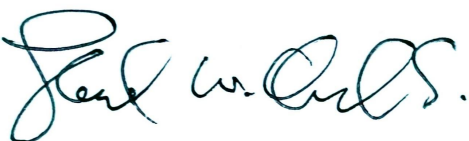
- Raw Material Suppliers – Provide certified RUO peptides that meet purity and labeling requirements.
- Third-Party Testing Laboratories – Conduct HPLC, MS, and purity testing to verify materials meet RUO specifications.
- Regulatory Consultants & Legal Advisors – Ensure continued compliance with Texas and federal laws, including FDA and Texas DSHS guidance.

Conclusion

Through our supplier certification process, rigorous quality control standards, regulatory monitoring, and legal oversight, Lonestar Research ensures that all peptides and raw materials comply with state and federal laws while maintaining the highest quality standards for research applications. If additional compliance documentation is required, we are happy to provide supporting records upon request.

For any further inquiries, please contact us at support@lonestarlaboratory.org or (512) 222-8436.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jeff W. Childs".

Lloyd Armbrust
Compliance, Lonestar Research