

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

lab@lonestarlaboratory.org
(512) 222-8436

January 1, 2025

To Whom It May Concern:

This letter serves as a formal statement of compliance regarding the operations of Lonestar Research, a division of Lonestar Services, LLC, in relation to both federal and state statutes governing the sale, distribution, and use of Research Use Only (RUO) peptides and raw materials. Lonestar Research exclusively provides RUO-designated materials to qualified research institutions and authorized individuals conducting legitimate scientific research, ensuring full compliance with Texas law and applicable federal regulations, including but not limited to:

- 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 Deceptive Trade Practices Act ([Texas Business & Commerce Code § 17.41 et seq.](#))
- Texas Controlled Substances Act ([Texas Health & Safety Code § 481.001 et seq.](#))
- Federal Food, Drug, and Cosmetic Act (FDCA) ([21 U.S.C. § 301 et seq.](#))
- FDA RUO Labeling & Distribution Requirements ([21 C.F.R. § 809.10\(c\)](#))
- Prohibited Acts & Misbranding ([21 U.S.C. § 331 & 352](#))

1. Definitions

For purposes of this letter, the following definitions shall apply:

1.1. Research Use Only (RUO) Materials: Substances explicitly labeled "For Research Use Only – Not for Human or Veterinary Use", which are not approved for medical, diagnostic, or therapeutic applications and are restricted to in vitro laboratory and scientific research.

1.2. Dangerous Drug: As defined under Texas Health & Safety Code § 483.001(2), any drug that is unsafe for self-medication and is not included in Schedules I through V or Penalty Groups 1 through 4 of the Texas Controlled Substances Act, and that bears or is required to bear the legend "Rx only" or similar prescription-required language.

1.3. Controlled Substance: Any chemical or compound listed in Texas Health & Safety Code § 481.001 et seq., including but not limited to substances classified under Penalty Groups 1 through 4.

1.4. Research Institution & Authorized Researchers: A university, laboratory, biotechnology research facility, private research organization, or an individual affiliated with a research entity and legally authorized under applicable state and federal law to conduct scientific research. Lonestar Research only permits sales to entities or individuals with a documented scientific research function and reserves the right to deny transactions or terminate existing agreements at its discretion.

1.5. Misbranded Drug: Any product that fails to meet labeling requirements under Texas Health & Safety Code § 431.021 and 21 U.S.C. § 352, including failure to include necessary disclaimers, misrepresentation of research chemicals as therapeutic agents, or sale without required FDA approvals.

2. Business Operations and Compliance with Texas and Federal Law

2.1. Verification of Research Status and Lab Agreement

Lonestar Research restricts the sale of RUO materials exclusively to verified research institutions and authorized researchers in compliance with 21 C.F.R. § 809.10(c) and Texas Dangerous Drug Act § 483.042.

Purchasers must sign a legally binding Research Use & Confidentiality Agreement prior to purchasing materials. The agreement requires:

1. Certification that all purchased materials will be used exclusively for in vitro research and will not be administered to humans or animals in any manner, including but not limited to ingestion, injection, inhalation, topical application, or implantation.
2. Acknowledgment that resale, repackaging, or distribution of RUO materials to third parties is prohibited without prior written authorization.
3. Acceptance of full legal responsibility for ensuring compliance with applicable research safety laws and regulations.

Lonestar Research reserves the right to refuse sales or terminate any agreement if it has reason to believe a purchaser may be using or distributing materials in violation of state or federal law.

2.2. Reporting of Non-Compliant Purchasers

Where applicable, any individual or entity found to be misusing, reselling, or repurposing RUO materials for unauthorized applications will be reported to the Texas Department of State Health Services (DSHS) and, the FDA or other relevant regulatory agencies.

2.3. No Prescription Drugs or Controlled Substances

Lonestar Research does not sell any product classified as a prescription drug or controlled substance under Texas or federal law.

2.4. Prohibition of Human and Veterinary Applications

To ensure compliance with 21 U.S.C. § 331 (Prohibited Acts) and Texas Dangerous Drug Act § 483.042, Lonestar Research enforces the following policies:

1. All customers must certify that no RUO materials will be administered to humans or animals in any manner.
 2. Customers acknowledge that repackaging, relabeling, or resale without prior authorization is prohibited.
 3. Marketing, advertising, or promoting materials for medical treatment, drug formulation, or performance enhancement is strictly forbidden.
-

3. Compliance & Internal Controls

3.1. Sales and Distribution Controls

- No sales to the general public, clinics, or medical facilities.
- Purchases are restricted to verified research institutions and authorized researchers.
- All transactions require a signed Research Use & Confidentiality Agreement.

3.2. Importation and Supplier Compliance

- All raw materials are sourced from cGMP-compliant manufacturers to meet FDA importation standards.
- Each batch undergoes HPLC purity testing ($\geq 98\%$) to verify research-grade quality.

3.3. Record-Keeping and Auditing

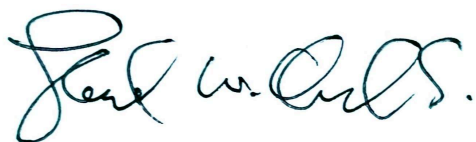
- Transaction records and purchaser attestations are retained for a minimum of five (5) years.
 - Internal audits ensure compliance with Texas and federal statutory requirements.
-

4. Statement of Compliance

Lonestar Research operates in full compliance with:

- Texas Dangerous Drug Act (Texas Health & Safety Code § 483.001 et seq.)
- Texas Food, Drug & Cosmetic Act (Texas Health & Safety Code § 431.001 et seq.)
- Texas Deceptive Trade Practices Act (Texas Business & Commerce Code § 17.41 et seq.)
- Texas Controlled Substances Act (Texas Health & Safety Code § 481.001 et seq.)
- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.)
- FDA RUO Labeling & Distribution Requirements (21 C.F.R. § 809.10(c))
- Prohibited Acts & Misbranding (21 U.S.C. § 331 & 352)

Sincerely,

A handwritten signature in blue ink, appearing to read "Lloyd Armbrust". The signature is fluid and cursive, with a large initial "L" and "A".

Lloyd Armbrust
Compliance, Lonestar Research