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NSF/ANSI Homeopathic Drug Products Standards Project

Purpose, Rationale, Scope, and Limitations

1. Why We Are Undertaking This NSF/ANSI Project

The homeopathic industry currently lacks a formal ANSI-developed consensus standard that addresses the unique manufacturing and labeling considerations of Homeopathic Drug Products (HDPs). This project is being initiated to:

- **Fill a standards gap**: No ANSI standard exists today for homeopathic drug manufacturing.
- **Respond to FDA interest**: FDA has encouraged the development of clear, operational standards that can support consistent inspection and regulatory oversight.
- **Demonstrate responsible self-regulation**: The industry seeks to show that it can proactively establish credible, auditable, and science-aligned manufacturing expectations.

Together, these drivers support a more predictable regulatory environment and help preserve access to the full range of homeopathic medicines.

2. What This Project Is Intended to Achieve

The goal is to develop voluntary ANSI consensus standards that:

- Are aligned with existing federal drug GMPs (21 CFR Parts 210 & 211).
- Provide a structured, homeopathy-specific framework that the FDA may reference .
- Once the standard is published, any certifying body that wants to audit this standard goes through an accreditation process with ANSI to verify its competence to certify to the standard. ANSI will post that list, and a manufacturer can reach out to any of those CBs for auditing. If they pass, they are able to place the seal on their product.

These standards will not replace federal law but will clarify how existing GMP principles apply to homeopathic manufacturing.

3. What Areas the Standard Will Cover

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The ANSI standard will address the full lifecycle of homeopathic drug manufacturing, including:

- Quality System Requirements
- Facilities and Equipment Controls
- Materials and Starting Material Controls
- Production and Attenuation Processes
- Packaging and Labeling Controls
- Laboratory Controls and Finished Product Testing

This structure mirrors the six-system inspection model used by FDA, ensuring the standard is immediately usable by regulators and manufacturers.

4. Products to Which the Standard Applies

The standard will apply broadly to all products labeled as homeopathic, including:

- Single-ingredient homeopathic drug products
- Combination homeopathic drug products
- Products with HPUS monographs
- Products without HPUS monographs (non-compendial)

This ensures the standard is inclusive of the full marketplace and aligned with the FDA's statutory authority, which is not limited to HPUS-recognized articles.

5. Limitations of the Standard

To maintain clarity, neutrality, and regulatory appropriateness, the standard will **not**:

- Establish requirements for clinical effectiveness or therapeutic validity, which falls outside of labeling/indications..
- Determine which homeopathic products may or may not be legally marketed (this is determined by the FDA).
- Replace, modify, or supersede any statutory or regulatory requirement under the Federal Food, Drug, and Cosmetic Act.
- Exempt any manufacturer from FDA inspection, enforcement, or compliance obligations.
- Replace the Homeopathic Pharmacopoeia of the United States (HPUS) or other pharmacopeias.

The standard is a manufacturing and labeling framework, not a clinical or regulatory gatekeeping tool.

6. Summary Statement

This NSF/ANSI project is not an attempt to redefine homeopathy or restrict the marketplace. Its purpose is to create a clear, credible, and operational standard that:

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- Supports FDA's ability to evaluate homeopathic drug products consistently.
- Helps manufacturers understand and meet appropriate GMP expectations.
- Strengthens consumer and practitioner confidence.
- Provides a stable regulatory foundation for the future of homeopathic medicines.

It is a practical, consensus-driven solution to a long-standing regulatory gap.

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