

THE DEVELOPMENT OF AN ANSI STANDARD FOR HOMEOPATHIC PRODUCTS

The NHPCB is a non-profit 501(c)(3) public charity, established in 2022 by the American Institute of Homeopathy (AIH), the oldest extant national medical society in the U.S., founded in 1844. AIH acted from concern that the Food and Drug Administration's (FDA), intended withdrawal of the Compliance Policy Guide that had provided a legally recognized pathway to the market for homeopathic products, and the lack of agency expertise resulting in the application of inappropriate, pharmaceutical-specific standards to their manufacturing, would result in increasing loss of access to safe homeopathic products by healthcare providers and consumers. AIH intended for NHPCB certification of companies and products to demonstrate to the FDA and the public that homeopathic products prepared and labeled according to homeopathic-appropriate standards were safe.

The charitable mission of the NHPCB is “to advance public health by creating standards to identify products that are properly formulated and labeled as homeopathic and contain no non-homeopathic active ingredients and developing procedures for certifying products that have been verified as meeting those standards, in order to promote consumer safety and choice and the confidence of healthcare professionals who use homeopathic products in their practices.”

As the first phase of developing a certification program to assure safety and quality in homeopathic products, the NHPCB developed an initial set of draft standards, which were circulated to the community and revised to reflect comments. The initial standards applied only to single ingredients and combination products listed in the Homeopathic Pharmacopeia of the United States (HPUS); the FDA, however, had expressed concerns to AIH representatives in meetings going back several years that HPUS guidelines were not developed by an open consensus process.

The AIH provided the NHPCB draft initial standards to the FDA and solicited its feedback. The FDA responded in writing that, while it could not recognize the proposed standards because the NHPCB was not following a robust standards development process accredited by a neutral party, “[W]e remain positive about the prospect that robust, accredited standards for homeopathic products could be beneficial to both the industry and consumers. If AIH decides to engage in a standard setting process that adheres to accepted principles of standards development, FDA would welcome the opportunity to provide our perspective and expertise.”

In response, the AIH notified the FDA that the NHPCB intended to pursue an ANSI-accredited standard development process, in response to which the FDA wrote, “[W]e are pleased to know that you are committed to pursuing American National

Standards Institute (ANSI) accreditation for your standards development process. Once NHPCB has adopted a standards development process that follows the foundational principles of standards development, including independent accreditation (e.g. by ANSI), we are hopeful about the potential of standards to provide reliable and clear guidance to industry, and give consumers assurance regarding the quality of their products.”

In February, 2025, the NHPCB engaged NSF International (NSF), a globally-recognized standard-setting and certification organization, to develop a standard for homeopathic products that would meet ANSI requirements for an open, fair, and balanced consensus process in which all directly interested parties may participate, no single group dominates, all views and objections are considered and concerted efforts made to resolve them, appeals may be made on due process grounds, and the public is informed.

The NHPCB is funding the cost of NSF’s services through public and foundation donations. A majority of the NHPCB board of directors is elected by the AIH and there are no industry members on the board. The NHPCB draft standards have been shared with NSF, and NHPCB has consulted with NSF staff to identify directly and materially interested parties whose experience and perspectives would provide valuable input to the standard. NHPCB has also reached out to the community to encourage interested parties to apply.

NSF has filed a Project Initiation Notice (PINS) with ANSI. NSF staff have received and reviewed applications from individuals who wished to be included in the process, either as voting members of the Joint Committee (JC) that will adopt the standard or as observers (who may participate equally in all activities of the Joint Committee except the final voting), and accepted just under 50 applicants. Participants include individuals who are directors, officers, or members of the NHPCB, the AIH, the Homeopathic Pharmacopeia Convention of the United States, the American Association of Homeopathic Products, the U.S. Pharmacopeia, research, certifying, education, public health, and consumer organizations, homeopaths, naturopaths, physicians, manufacturers, brand owners, consultants, attorneys, and individual consumers.

The process will be chaired and staffed by NSF, which is responsible for ensuring that, in compliance with ANSI accreditation requirements, the JC has a balance of participants who bring industry, user, and public health/regulatory perspectives, and no entity or interest dominates or unfairly influences the outcome of the process. The result will be a U.S. standard for homeopathic products on which regulators, industry, practitioners, certifying organizations, and consumers can rely, and which will help ensure the continued availability of safe, quality homeopathic products.