August 31, 2023

Dr. Ronald D. Whitmont, MD
American Institute of Homeopathy
6250 Route 9
Rhinebeck, NY 12572
By email: homeopathicmd@gmail.com

Dear Dr. Whitmont,

The Food and Drug Administration (FDA) appreciates the engagement we've had with the American Institute of Homeopathy (AIH) regarding mechanisms to better ensure the quality of homeopathic products. AIH requested FDA's input on the "Certified Homeopathic" Seal administered by AIH's National Homeopathic Product Certification Board (NHPCB). We had discussed the potential for an AIH standard development process to provide reliable and clear guidance to industry and give consumers assurance regarding the quality of their products. Our discussions anticipated that AIH's standard development process would follow the foundational principles of standards development, including independent accreditation (e.g. by the American National Standards Institute (ANSI)). We were hopeful about the potential of that approach.

We reviewed your proposed Seal program, and as well as information made available about the program on your public website (https://certifiedhomeopathic.org/). It appears that AIH has decided not to follow the standards development approach to create the Seal. Such an approach would have included the globally accepted elements of openness, balance, due process, appeals process and consensus. Adhering to these standards would have required, among other elements, transparency about how the proposed standards were developed (and any conflicts of interest among the individuals involved), a robust process of seeking comment and reaching consensus, and accreditation by a neutral party. AIH and the neutral accreditor would have also ensured the impartiality of those developing the standards. Using this process would have helped ensure the effectiveness, relevance, and technical accuracy of the resulting standards.

A robust standards development process is critically important to achieve the homeopathics product quality goals we had been discussing, which we thought were shared goals. Without reliable standards to back it up, the Seal program does not provide stakeholders – consumers, retailers, or FDA – a basis to draw meaningful conclusions about the quality of homeopathic products. It also has the potential to be misused as a marketing tool.

Additionally, the existing proposal reflects some significant misunderstandings of key FDA standards and processes. For example, certain key HPUS definitions (as relied upon by NHPCB) are not aligned with FDA's current good manufacturing practice (CGMP) statute, regulations, and guidance. Additionally, FDA's Inactive Ingredient Database (IID) is not described correctly throughout the document. We are also concerned that if a product already has a Seal and newly determined potentially toxic ingredients are identified, NHPCB does not require individual testing of those ingredients until the time of the next NHPCB Seal renewal. This could enable

potentially toxic ingredients to reach the market between Seal renewals, leading to risk to patients. Following accepted principles for standards development, including a public comment process, would have given FDA and other stakeholders an opportunity to review and offer input to resolve these and other concerns.

Following a robust standard development process will be necessary for FDA to give any weight to the Seal program. Without that, any suggestion that FDA helped develop or will use the Seal, or that the standards are verified standards, may mislead the public. We ask that your website remove such implications, including the "Benefits to FDA" section. If AIH is unwilling to take appropriate steps to remove these references, FDA will consider further action as appropriate. We also encourage you to revisit other claims on your website that may misleadingly suggest that products with the Seal meet FDA standards, such as language indicating that the Seal provides assurances to consumers that products bearing the seal "are safe and of a quality they can trust."

We 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.

Again, we thank you for the opportunity to engage.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2023.09.01 14:38:50 -04'00'

Douglas C. Throckmorton, M.D.
Deputy Director for Regulatory Programs
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