

September 19, 2023

*Submitted via email*

Robert M. Califf  
Commissioner of Food and Drugs  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Califf:

The Center for Inquiry, Inc. is an educational 501(c)(3) nonprofit organization that exists to promote science, reason, freedom of inquiry, and humanist values.<sup>1</sup> CFI's vision is a world in which evidence, science, and compassion—rather than superstition, pseudoscience, or prejudice—guide public policy.<sup>2</sup> **Central to the organization's work is the promotion of science-based medicine and challenging pseudoscientific alternative medicine, including homeopathy.**

Recent news reports have indicated that an outside panel of experts voted unanimously “against the effectiveness of orally administered phenylephrine as a nasal decongestant, adding that no more trials were required to prove otherwise.”<sup>3</sup> This presents the Food and Drug Administration (FDA) with the choice as to whether to remove phenylephrine from its list of approved ingredients for over-the-counter (OTC) drugs, and thereby prevent medicines based on it from being sold over the counter.

We believe that this is precisely the way that regulation of OTC drugs should work. Consumers deserve protection from spending their hard-earned money on products that claim to treat various conditions but do not, in fact, work. The general public lacks medical expertise and relies on the FDA as a gatekeeper of medical products, thus ensuring that when purchasing OTC products, they are purchasing safe and effective treatments.

**The issue we would like to raise, however, is why homeopathy is not treated in the same way.** Homeopathic products are drugs under the federal Food, Drug, and Cosmetic Act of 1938. Their regulation falls under the purview of the FDA. As the FDA has made clear, “[t]here are no FDA-approved products labeled as homeopathic; this means that any product labeled as homeopathic is being marketed in the U.S. without FDA evaluation for safety or effectiveness.”<sup>4</sup>

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<sup>1</sup> <https://centerforinquiry.org/>

<sup>2</sup> <https://centerforinquiry.org/about/>

<sup>3</sup> <https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-panel-says-popular-decongestant-used-cold-medicines-ineffective-2023-09-12/>

<sup>4</sup> <https://www.fda.gov/drugs/information-drug-class/homeopathic-products>



Beyond not having been evaluated for safety and efficacy, homeopathic products do not, and cannot, work. **The pseudoscience upon which homeopathy is based is fundamentally flawed, and the FDA is aware of this. No credible scientific evidence demonstrates a curative effect of homeopathy above that of a placebo.**

This lack of basis is recognized by the National Center for Complementary and Integrative Health, part of the National Institutes of Health, which states “[t]here’s little evidence to support homeopathy as an effective treatment for any specific health condition.”<sup>5</sup> A meta study undertaken by the Australian National Health and Medical Research Council in 2015 concluded that “there are no health conditions for which there is reliable evidence that homeopathy is effective.”<sup>6</sup>

Homeopathy doesn’t work. Yet while the FDA debates whether products with phenylephrine should be available OTC, **Oscillococcinum, manufactured by Boiron, remains on pharmacy shelves with signs indicating its use as a treatment for colds and the flu.**<sup>7</sup> Oscillococcinum is a homeopathic preparation of *anas barbariae*. This “therapeutic” ingredient is, in fact, the heart and liver of the Muscovy duck. It is prepared to a homeopathic dilution of 200C, meaning, in plain English, that there is one part duck offal to 10<sup>400</sup> parts of water in the “treatment.” Given that research estimates there to be between 10<sup>78</sup> and 10<sup>82</sup> in the entirety of the observable universe,<sup>8</sup> it is a physical impossibility for there to be a single atom of duck offal left in the product.

Oscillococcinum is nothing more than a sugar pill. Evidence has shown it does not work. **We therefore request that the FDA remove it, along with all other homeopathic products, from OTC sale at pharmacies in the United States.**

CFI is currently involved in multiple lawsuits against homeopathic retailers (including CVS and Walmart) and manufacturers (including Boiron).<sup>9</sup> This does not, however, negate the responsibilities of the federal government to regulate in this area. The FDA has the authority and the evidence to remove homeopathic products from sale. It must act on them.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'N. Little', is positioned above the typed name and title.

Nicholas J. Little  
Vice President and General Counsel  
nlittle@centerforinquiry.org

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<sup>5</sup> <https://www.nccih.nih.gov/health/homeopathy>

<sup>6</sup> <https://www.nhmrc.gov.au/about-us/resources/homeopathy>

<sup>7</sup> <https://www.oscillo.com/>

<sup>8</sup> <https://www.universetoday.com/36302/atoms-in-the-universe/>

<sup>9</sup> <https://centerforinquiry.org/advocacy/office-of-consumer-protection-from-pseudoscience/>



Azhar Majeed  
*Director of Government Affairs*  
amajeed@centerforinquiry.org