April 08, 2020

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration
Staff and Industry (Docket No. FDA-2017-D-6580)

Dear Members of the Administration,

The Center for Inquiry (CFI) appreciates this opportunity to comment on the proposed final enforcement guidance for drug products labeled as homeopathic.

**CFI Is a Charitable Nonprofit Organization Dedicated to Advancing Evidence-Based Policy**

CFI is an educational and advocacy organization that promotes reason and scientific integrity in public affairs. CFI’s vision is a world where people value evidence and critical thinking, where superstition and prejudice subside, and where science and compassion guide public policy. Our comments are submitted not only on behalf of our organization, its employees, and its members but also on behalf of dozens of doctors and scientists associated with CFI and its affiliate program the Committee for Skeptical Inquiry (CSI)\(^1\) and CFI’s division, the Richard Dawkins Foundation for Reason & Science,\(^2\) with whom we work on these matters.

Since its inception, CFI has been a prominent advocate of evidence- and science-based policy in all branches of government. In 2016, CFI submitted an amicus brief to the Supreme Court arguing that a Texas law that restricted access to women’s reproductive health care was based on unscientific information gathered by an individual with no medical qualifications. The Court ruled in favor of CFI’s position.

In addition, CFI engages in civic education to improve scientific literacy in the United States. For example, in 2015 as a result of CFI and CSI’s efforts, the Associated Press announced that it

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1. [https://www.csicop.org/](https://www.csicop.org/)
2. [https://www.richarddawkins.net/](https://www.richarddawkins.net/)
would no longer use the term *skeptic* to describe individuals who reject the mainstream science of climate change.

A primary focus of CFI’s work is preventing public harm from policies, initiatives, or institutions that fail to adhere to known scientific facts or principles. The “alternative medicine” industry is such an institution.

One of the most egregious examples of harmful “alternative medicine” is homeopathy, a category of products based on the disproven eighteenth-century theory that when diluted to virtually nonexistent concentrations, otherwise toxic substances transfer unidentified healing properties to water molecules. Not only is this theory unsupported by evidence, it violates known properties of physics and chemistry.

In April 2015, CFI testified to the Food and Drug Administration (FDA) about homeopathy’s potential harm and the need to hold homeopathic drugs to the same standards of safety and efficacy as conventional medicine.

In November 2015, following the Federal Trade Commission’s (FTC) Homeopathic Medicine & Advertising Workshop, CFI filed comments urging the FTC to stop manufacturers from falsely advertising homeopathy’s safety or efficacy until such claims can be scientifically proven.

In November 2016, the FTC issued a staff report on the Homeopathic Medicine & Advertising Workshop that cited CFI’s comments. Concurrent with the report, the FTC issued new enforcement guidance for homeopathic products, which declared that homeopathic products cannot include claims of effectiveness without “competent and reliable scientific evidence.” If no such evidence exists, homeopathic products must state this fact clearly on their labeling and that the product’s claims are based only on eighteenth-century theories that have been discarded by modern science.

In July 2018, CFI filed suit against CVS Health, the largest retail pharmacy chain in the United States, for fraudulently marketing homeopathic products in the District of Columbia. In May 2019, CFI filed suit against Walmart, the largest retail chain in the world, for the same violation. Both cases are currently progressing.

**FDA’s Final Draft Enforcement Guidance Does Not Incorporate Concerns Expressed by CFI in Our Public Comment on FDA’s Initial Draft Enforcement Guidance**

In 2017, CFI submitted a public comment in response to the FDA’s issuance of draft enforcement guidance to replace CPG 400.400. In that comment, CFI expressed concern that

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3 Indeed, the level of dilution is often so high that it is impossible according to the laws of science that a single molecule of the original ingredient remains.
the draft guidance would make compliance more difficult and would jeopardize consumer health and safety. The present final guidance is extremely similar in substance to the 2017 initial draft guidance. Therefore, in addition to our present comment, CFI directs FDA’s attention to our 2017 draft enforcement guidance comment, in which we stated:

CFI believes that the suggested guidance does not adequately address the major issues posed by the marketing and sale of homeopathic products in the United States, and leaves patients vulnerable to significant harm caused by the inappropriate use and sale of homeopathic products. CFI has significant concerns that the draft guidance issued by the FDA represents a step back from the FDA’s responsibility to ensure that American consumers are protected from the harms caused by ineffectively labeled and inadequately tested homeopathic products. While the FDA has a responsibility to protect consumers from the dangers referenced in the proposed guidance, this alone is insufficient. CFI therefore requests that the FDA broaden its proposed enforcement priorities to include regulation of the testing and labeling of all homeopathic products.

The FDA itself, importantly, has also recognized that homeopathy is not effective. For example, the FDA has issued numerous warnings to consumers about the health risks of relying on homeopathic products to treat serious medical conditions. These include, for example, the FDA’s March 2015 warning against using homeopathic products that claim to treat asthma, an often life-threatening condition. In it, the FDA states “The U.S. Food and Drug Administration is warning consumers not to rely on asthma products labeled as homeopathic that are sold over-the-counter (OTC). These products have not been evaluated by the FDA for safety and effectiveness.” More recently, the FDA issued a warning to parents regarding the use of homeopathic baby teething products that contained belladonna, commonly known as Deadly Nightshade, describing them as “an unnecessary risk to infants and children,” and “urg[ing] consumers not to use these products.”

In September 2019, CFI Commissioned a Scientific Survey That Found Homeopathic Products Mislead Patients

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4 ID: FDA-2017-D-6580-3876
6 Id.
In September 2019, CFI published the results of a survey that it commissioned to measure the extent to which consumers are misled by homeopathic drug product marketing. The survey drew from a nationally representative sample of 1,000 adults, along with an oversample of 200 adults who reside in Washington, D.C., where CFI has filed suit against Walmart and CVS for fraudulently marketing homeopathic products.

CFI’s survey demonstrates that the sale and marketing of homeopathic drugs for self-limiting conditions undermines drug regulatory safety by blurring the line between FDA-approved OTC drugs, non-FDA approved homeopathic products, and dietary supplements. As a result, confused consumers unknowingly purchase ineffective and potentially unsafe homeopathic products. One in ten survey respondents reported having accidentally purchased a homeopathic drug product, having mistaken it for an FDA-approved, science-based drug. As a result, patients’ suffering is needlessly extended and aggravated because they unknowingly purchase homeopathic drugs instead of FDA-approved drugs that are safe and effective.

CFI’s research found that respondents were generally unfamiliar with the pseudoscientific principles of homeopathy. After having these principles explained to them, respondents’ trust in homeopathic products sharply declined.

Only 1 percent of respondents correctly identified *Anas barbaraiae*, the “active” ingredient in the widely marketed homeopathic drug Oscillococcinum, as the heart and liver of a Muscovy duck. Twenty-two percent of respondents thought that *Anas barbaraiae* was a medicine. Another 13 percent thought it was a vitamin, which would mean that *Anas barbaraiae* were regulated in the United States as a dietary supplement under the Dietary Supplement Health and Education Act (DSHEA). Fifty-nine percent of respondents were unsure. Once respondents were informed of the “active” ingredient, almost half (46 percent) viewed Oscillococcinum less favorably.

Among respondents who were not familiar with the theory of homeopathy or the contents of Oscillococcinum, when asked to evaluate the safety and efficacy of Oscillococcinum based only on the product label, 50 percent believed the product to be effective. Another 34 percent of respondents were unsure of its efficacy. Similarly, 57 percent of respondents believed Oscillococcinum to be safe, with another 29 percent unsure. Fifty-one percent of respondents believed that Oscillococcinum should be sold in the “Cough, Cold, and Flu” section of the pharmacy.

Yet when respondents were given information about the theory of homeopathy and the contents of Oscillococcinum, 15 percent shifted their view of the product from “effective” to

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“not effective,” bringing the total percentage of respondents who believed in its efficacy down from 50 to 35 percent. In addition, this information considerably reduced respondents’ uncertainty about the efficacy of Oscillococcinum. The percentage of respondents who were unsure about Oscillococcinum’s efficacy dropped from more than one third (34 percent) to just over one fifth (21 percent).

The percentage of respondents who believed that Oscillococcinum is safe declined from 57 percent to 51 percent. Overall, more than twice as many respondents shifted their view of Oscillococcinum toward “less safe” (21 percent) than those whose view shifted toward “more safe” (10 percent) on a four-point scale.

Asked whether they would be likely to purchase Oscillococcinum for use on themselves, 24 percent of respondents shifted their view toward “not likely” on a four-point scale.

The percentage of respondents who believe that Oscillococcinum should not be sold alongside non-homeopathic drugs increased ten points, from 22 percent to 32 percent. All major subgroups identified by the survey in the categories of gender, race, age, college education, and region registered a decline. A plurality of respondents (31 percent) agreed with the statement “It is misleading, and even deceptive, to sell homeopathic OTC drugs on a shelf next to non-homeopathic OTC drugs in the Cough, Cold & Flu section without a warning.”

Respondents expressed a greater degree of trust in large retail pharmacies than in the Food and Drug Administration. Asked whether they trust various institutions, a net 49 percent of respondents declared trust in Walmart, the nation’s largest consumer retail chain. Similarly, a net 54 percent of respondents declared trust in CVS, which operates the largest pharmacy retail chain. In contrast, a net 36 percent of respondents agreed that they trust the FDA. This fragile trust is crucial to the effectiveness of FDA’s OTC drug regulatory regime. It is undermined when non-FDA approved homeopathic products are marketed as drugs alongside FDA-approved drugs. Only the most discerning patients are likely to distinguish between approved drugs and non-approved homeopathic products. A plurality of respondents (46 percent) choose a cold and flu remedy by selecting a product from “the appropriate aisle” of a pharmacy without consulting a pharmacist or doctor. Therefore, people are likely to view the inclusion of homeopathic products in drug aisles as an implicit endorsement of the product’s safety and efficacy. Indeed, 10 percent of respondents reported that they have accidentally purchased a homeopathic drug when they intended to purchase a non-homeopathic drug. Another 20 percent of respondents were unsure, suggesting that homeopathic product labeling and placement is so vague and deceptive that they could not reliably recall whether they have purchased a homeopathic product.

To Uphold the Provisions of the Food, Drug, and Cosmetic Act of 1938, FDA’s Enforcement Guidance Must Assume That Homeopathic Products Are Unsafe and Ineffective
FDA’s enforcement guidance for homeopathic products assumes that manufacturers are acting in good faith to comply with federal laws including the Food, Drug, and Cosmetic Act of 1938 (FD&C Act). This “benefit of the doubt” for manufacturers is unjustified and places patients at risk. Homeopathy is an inherently predatory industry that deceptively markets plain water and sugar pills as a “natural” alternative to FDA-approved drugs that have successfully withstood scientific scrutiny in premarket clinical trials. The theory of homeopathy is so scientifically implausible that manufacturers of these products cannot be assumed to act in good faith in accordance with drug safety and efficacy and consumer protection laws. In proof of point, the theory combines these pseudoscientific concepts:

- The “law of similar” or “let likes be cured by likes.” This is the belief that a medical condition can in fact be treated by administering a diluted substance observed to cause it or similar symptoms. For this reason, homeopathic products often consist of diluted solutions of toxic substances (such as the use of Deadly Nightshade in baby teething products as noted supra).

- The “law of infinitesimal doses.” This is a belief that the more one dilutes an ingredient, the more powerful it becomes. As a result, many homeopathic products are diluted beyond Avogadro’s Number, the point at which the final product, however large the dose taken, likely no longer contains even a molecule of the supposed active ingredient.  

- “Essence” and “water memory.” The beliefs that substances added to water impart their “essence” onto the water molecules themselves, and that water retains a “memory” of things that have been in previous contact with it. This entirely unsubstantiated supposition is the invention of homeopaths who recognize the impossibility of reconciling the technique of extreme dilution with the laws of chemistry. So, although a finished homeopathic solution may no longer contain any molecules of the actual supposed remedy, homeopaths contend that the water maintains its power.

- “Miasm theory” and “vital force/vital principle theory.” The hypotheses that all diseases are caused by one of three offending “miasms”—psora, syphilis, and sycosis—which disrupt the “vital force” at the core of a human being. As a system of vitalism, homeopathic products are meant to address these miasms.

- “The law of susceptibility.” The hypothesis that negative thinking can attract said miasms and lead to illness.

CFI notes that the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH) has rejected the efficacy of homeopathy, stating, “There’s...”

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9 For example, Oscillococcinum, a homeopathic preparation that is claimed to treat influenza, consists of the liver and heart of a particular kind of duck, diluted to a level of 200C, leaving one part duck offal to 10^400 parts water. By way of comparison, current estimates suggest that the known universe contains up to 10^82 atoms.
little evidence to support homeopathy as an effective treatment for any specific health condition.”

The sale of homeopathic products will therefore cause unknowing patients to delay or reject evidence-based treatments with FDA-approved drugs, causing them unnecessary suffering and possibly exacerbating the seriousness of their disease and making it more difficult to treat.

As FDA notes in its final enforcement guidance, homeopathic products are not generally recognized as safe and effective “by qualified experts for use under the conditions prescribed, recommended, or suggested in the labeling (GRAS/E).” Therefore, in accordance with Section 201 (p) of the FD&C Act, all homeopathic products are classified as “New Drugs.” FDA makes GRAS/E determinations for OTC drugs marketed under the OTC Drug Review but the agency deferred review of homeopathic products in 1972 and has not reviewed any homeopathic preparation that is currently marketed as a drug. CFI believes that a comprehensive FDA review of the homeopathic preparations described in the Homeopathic Pharmacopoeia of the United States (HPUS) is vitally necessary to protect patients from unsafe and/or ineffective new drugs. FDA should conduct this decades-overdue review before making further revisions to policy or guidance in this area. Nevertheless, in the absence of such review and in light of the facts described above, FDA should assume, in its enforcement guidance and in all other considerations, that homeopathic preparations are neither safe nor effective at treating any disease.

In addition, in recent years governments in several countries have banned the sale of homeopathic products, severely restricted their permitted uses, repealed government funding for the use or purchase of these products, or proposed doing so, explicitly in response to the abundant scientific evidence that these products do not and cannot safely and effectively treat any known health condition. These countries include Canada, France, Australia, the United Kingdom, and Spain.

**FDA’s Final Enforcement Guidance Should Include Requirements That Explicitly Reference the Relevant Provisions of the FD&C Act**

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10 https://nccih.nih.gov/health/homeopathy#hed1


12 [Visit](https://www.cbc.ca/news/health/government-funding-homeopaths-honduras-1.5046056)

13 [Visit](https://www.theguardian.com/world/2019/jul/10/france-to-stop-reimbursing-patients-for-homeopathic-treatment)


15 [Visit](https://www.theguardian.com/lifeandstyle/2017/jul/21/a-misuse-of-scarce-funds-nhs-to-end-prescription-of-homeopathic-remedies)

16 [Visit](https://elpais.com/elpais/2018/11/14/inenglish/1542203925_514487.html)
The draft guidance eliminates the detailed references to relevant provisions of the FD&C Act that were included in CPG 400.400. Homeopathic drug manufacturers will likely interpret this omission as FDA’s tacit permission to unlawfully market unapproved homeopathic preparations as drugs so long as manufacturers avoid only the most egregious violations. This in turn will undermine the perceived legitimacy of the FDA approval process and the importance of premarket scientific research on the safety and efficacy of new drugs.

Any enforcement guidance issued by FDA should include specific instructions for homeopathic manufacturers to comply with the requirements of the FD&C Act with references to specific provisions. For example, in justifying its requirement to translate product ingredient names from Latin to English, CPG 400.400 referred to multiple provisions of the FD&C Act and corresponding federal regulations: Section 502(e)(3) of the Act and 21 CFR 201.10 require that drug products bear an established name. Section 502(c) of the Act and 21 CFR 201.15(c)(1) require that all drug product labeling be in English.

The Requirement Established in CPG 400.400 to List Ingredient Names in English Is Critical to Eliminating Unnecessary Risks Posed by Unapproved New Drugs and Should Not Be Repealed

CPG 400.400, first issued in May 1988, required homeopathic drug manufacturers to translate active ingredients from Latin to their common English names on product labeling “by June 11, 1990, or as current labeling stocks are depleted, whichever occurs first.” Since then, homeopathy has grown to an industry of more than $1 billion annually. Today, nearly thirty years later, many homeopathic drug manufacturers are still in violation of this commonsense requirement.

In the enclosed documents, Figure 1 is a photograph of a homeopathic drug product, Sinusalia, taken by CFI on November 27, 2018. Sinusalia is manufactured by Boiron, one of the largest manufacturers of homeopathic drug products in both the United States and the world. More than twenty-eight years after the deadline imposed by FDA, Boiron continues to market homeopathic drug products with ingredient names listed only in Latin.

Figure 2 is a photograph of the same homeopathic drug product, Sinusalia, taken by CFI on November 27, 2018, with CFI’s translation of the toxic active ingredients from Latin to English superimposed on the product ingredient label.

Figure 3 is a photograph of a homeopathic drug product, SinusCalm, purchased by CFI on September 16, 2019. SinusCalm is also manufactured by Boiron. SinusCalm contains the same ingredients as Sinusalia and is apparently an identical product marketed under a new name. Despite having obviously changed its labeling stocks to accommodate the new product name, Boiron continues to list the active ingredients exclusively in Latin.
These flagrant violations deceive consumers by making it appear that the common toxins, which comprise homeopathy’s “active” ingredients, were evaluated by medical specialists educated in professional jargon. Despite FDA’s claim that CPG 400.400 is outdated, the requirement to translate ingredient names from Latin to English is more relevant than ever. To remove this requirement effectively condones this deceptive practice and tacitly encourages homeopathic manufacturers to violate other FDA regulations. FDA should retain this requirement and renew its commitment to enforcement of it. Clearly, the requirement to list active ingredients in the language of fluency of most Americans is a necessary component of FDA’s guidance.

If you have any questions about our comments, please contact Jason Lemieux at jlemieux@centerforinquiry.org.

Sincerely,

Robyn Blumner
President and CEO
Center for Inquiry

Nicholas Little
Vice President and General Counsel, Legal Director
Center for Inquiry

Jason Lemieux
Director of Government Affairs
Center for Inquiry
Enclosures:

**Figure 1** – Boiron Homeopathic Drug Sinusalia in violation of FDA’s requirement to translate active ingredients from Latin to English. Observed on November 27, 2018.

**Figure 2** – Boiron Homeopathic Drug Sinusalia with CFI’s translation of toxic active ingredients from Latin to English. Observed on November 27, 2018.

**Figure 3** – Boiron Homeopathic Drug SinusCalm, with ingredients identical to Boiron’s discontinued product Sinusalia, in violation of FDA’s requirement to translate active ingredients from Latin to English. Purchased on September 16, 2019.
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