William L. Schwemer
289 Morningwood Lane,
Wirtz, VA 24184

May 13, 2020

Re: Docket No. FDA-2013-P-1378

Dear Mr. Schwemer:

This letter responds to the citizen petition dated October 22, 2013 (Petition), that you submitted to the Food and Drug Administration (FDA or Agency). The Petition requests that FDA update Compliance Policy Guide Section 400.400 (CPG 400.400) entitled "Conditions Under Which Homeopathic Drugs May be Marketed." More specifically, you ask that CPG 400.400 be updated:

> to ensure that consumers of Homeopathic OTC drugs will have the necessary label information to make informed choices and further, to ensure that manufacturers and distributors have clear standards to enable fair competition in the marketing of Allopathic (also referred to as "conventional" drugs) and Homeopathic drugs.

Petition at 1.

You also state that:

> [s]teps need to be taken by FDA to pervasively regulate OTC Homeopathic drug products under rules similar to those set forth in the regulations "Over-The-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and effective and Not Misbranded" (21 CFR Part 330) and "Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling" commonly referred to as the "Drug Facts" rules (21 CFR 201.66).

Petition at 1.

Additionally, you suggest that FDA:

> consider consulting with the National Institutes of Health's Center for Complementary and Alternative Medicines (NCCAM), and others as necessary, then publishing in the Federal Register an Advanced Notice of Proposed Rulemaking that would set forth a proposal or options for revising the Agency's current policies and/or procedures.

Petition at 1.

We have carefully considered the information submitted in the Petition and your supplement to the Petition dated March 31, 2015. For the reasons stated below, the Petition is denied.

I. BACKGROUND

Homeopathy is an alternative medical practice that has a historical basis in theory and practice first systematized in the late 1700s. Homeopathy is generally based on two main principles: (1) a substance that causes symptoms in a healthy person can be used in diluted form to treat symptoms and illnesses (known as *like-cures-like*) and (2) the more diluted the substance, the more potent it is (known as the *law of infinitesimals*).

The definition of "drug" in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g)(1)) includes articles recognized in the Homeopathic Pharmacopoeia of the United States or any supplement to it. As such, homeopathic drugs are subject to the same statutory framework that applies to other drugs marketed in the United States. Generally, a drug, including a homeopathic drug product,[1] is considered a "new drug" if it is not generally recognized by qualified experts as safe and effective (GRAS/E) for its labeled uses (section 201(p) of the FD&C Act). Under the OTC Drug Review, FDA makes GRAS/E determinations for nonprescription drugs marketed without an approved drug application (see section 505G of the FD&C Act; 21 CFR Part 330). FDA has not reviewed any homeopathic drug products under the OTC Drug Review because the Agency placed homeopathic drug products in a separate category and deferred consideration of them (37 FR 9464 at 9466 (May 11, 1972)).

Under section 505(a) of the FD&C Act (21 U.S.C. 355(a)), before any "new drug" is marketed, it must be the subject of an approved application submitted pursuant to section 505(b) or section 505(j) of the FD&C Act. The requirements in section 505 of the FD&C Act apply to biological products regulated under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262); however, a biological product with an approved license under section 351(a) of the PHS Act is not required to have an approved application under section 505 of the FD&C Act (see section 351(j) of the PHS Act; 42 U.S.C. 262(j)). Accordingly, absent a determination that a homeopathic drug product is not a "new drug" under section 201(p), all homeopathic drug products are subject to the premarket approval requirements in section 505 of the FD&C Act or section 351 of the PHS Act. Currently, no homeopathic drug products are approved by FDA.

In May 1988, FDA's Center for Drug Evaluation and Research issued CPG 400.400, entitled "Conditions Under Which Homeopathic Drugs May be Marketed." CPG 400.400 described an enforcement policy regarding homeopathic drug products.

As a result of the growth of the industry and passage of more than 2 decades since the issuance of CPG 400.400, FDA announced on March 27, 2015, that it was evaluating the regulatory framework for homeopathic products.[2] In April 2015, FDA held a public hearing to obtain

[1] For purposes of this response, we refer to a 'homeopathic drug product' as a drug product that is labeled as "homeopathic."

[2] 59 FR 16327, March 27, 2015, "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing."

information and comments from stakeholders about the current use of homeopathic drug products, as well as the Agency's regulatory framework for such products.[3] FDA sought broad public input on its enforcement policies related to homeopathic drug products to better promote and protect the public health.

On December 20, 2017, after extensive Agency evaluation including consideration of the public input, FDA issued a draft guidance entitled *Drug Products Labeled as Homeopathic*. The draft guidance detailed a risk-based enforcement policy, prioritizing enforcement and regulatory actions for certain categories of homeopathic products that potentially pose higher risk to public health.

In response to comments received, we revised the draft guidance and reissued it on October 25, 2019 (revised draft guidance)[4] to enable the public to review and comment before it is finalized. In particular, we have added a definition of "homeopathic drug product" for purposes of the guidance, added additional explanation of some of the safety issues that contributed to the development of the draft guidance, and clarified the intent to prioritize enforcement and regulatory actions with respect to premarket approval requirements involving homeopathic products that are marketed without required FDA approval. In addition, on that same date, FDA announced the withdrawal of CPG 400.400.[5]

The notice of availability for the revised draft guidance requested comments by January 23, 2020, so they may be considered before FDA begins work on the final version of the guidance. However, FDA subsequently extended the comment period for an additional 60 days, until March 23, 2020,[6] and then further extended the comment period until May 22, 2020.

II. DISCUSSION

As described above, the Petition asks FDA to update CPG 400.400 to ensure that homeopathic OTC drugs are required to include certain information in their labeling to enable consumers of such drugs to make informed choices and to set forth clear standards to facilitate fair competition in the marketing of allopathic and homeopathic drugs (Petition at 1). The Petition also requests that the Agency employ a similar regulatory framework for both OTC homeopathic drugs and allopathic OTC drugs (Petition at 1). In

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[3] Docket No. FDA-2015-N-0540; available at https://www.regulations.gov/docket?D=FDA-2015-N-0540.

[4] 84 FR 57441, October 25, 2019, "Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry." Available at https://www.fda.gov/media/131978/download. When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[5] 84 FR 57439 October 25, 2019, "Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance."

[6] 85 FR 918, January 8, 2020, "Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry; Extension of Comment Period."

addition, the Petition suggests that FDA consult with NCCAM and publish in the *Federal Register* an Advance Notice of Proposed Rulemaking that would set forth a proposal or options for revising the agency's current policies and/or procedures (Petition at 1).

Rather than revising CPG 400.400, the Agency has determined that it is in the best interest of public health to withdraw the CPG and issue a revised draft guidance, which, when finalized, will describe FDA's current thinking regarding our intended prioritization of any enforcement and regulatory actions against unapproved homeopathic drugs. As FDA explained in its Federal Register notice announcing the withdrawal of the CPG:

> Because CPG 400.400 is inconsistent with the Agency's risk-based approach to enforcement generally, it does not accurately reflect the Agency's current thinking. When the draft guidance is finalized, it will specify the categories of products that the Agency intends to prioritize for enforcement. In the interim, before the draft guidance is finalized, FDA intends to apply its general approach to prioritizing regulatory and enforcement action, which involves risk-based prioritization in light of all the facts of a given circumstance. Risk-based enforcement best reflects FDA's public health priorities.[7]

We recognize that in your Petition you requested that FDA undertake rulemaking rather than withdrawing the CPG and issuing new guidance. However, we note that your Petition acknowledged that "the Agency may choose a different approach to resolve the problems described herein" (Petition at 1). FDA assessed your requests for rulemaking in light of its other options and resource constraints. FDA operates with limited resources, and it evaluates options in terms of the extent of a potential risk, the time and delay that would accompany these actions, and the availability of other means to address concerns. At this time, we believe that rulemaking would not be the most efficient and effective use of FDA's resources. Instead, we intend to proceed with finalizing the revised draft guidance to reflect FDA's risk-based enforcement priorities for homeopathic drug products, as described above, taking stakeholder comments into account. Under the approach described in the revised draft guidance, FDA would prioritize enforcement and regulatory actions for certain categories of homeopathic products that potentially pose higher risk to public health, including, e.g., products intended to be used for the treatment or prevention of serious and/or life-threatening diseases or conditions. FDA will consider further data and information that might emerge on this topic. Accordingly, we are denying your requests, including your request that FDA revise CPG 400.400 in the manner you describe and your request that FDA consult with NCCAM and publish in the *Federal Register* an Advance Notice of Proposed Rulemaking that would set forth a proposal or option for revising CPG 400.400 or any other agency policies and/or procedures with respect to homeopathic drugs.

FDA's response to the Petition comes after extensive public discussion of our regulatory framework for homeopathic drug products, including the April 2015 public hearing and an

[7] 84 FR 57439, 57440 October 25, 2019, "Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance." The notice also explained that absent a determination that a homeopathic drug product is not a "new drug" under section 201(p) [of the FD&C Act], all homeopathic drug products are subject to the premarket approval requirements in section 505 of the FD&C Act or section 351 of the PHS Act.

extended open docket on our revised draft guidance. The Agency has listened carefully to comments from interested stakeholders, some advocating tighter regulation of homeopathic drug products and others advocating a hands-off approach. FDA appreciates the time stakeholders have taken to share their views, including your December 29, 2017 comments to the draft guidance docket. Should you have further comments you wish to share with the Agency, please submit them before May 22, 2020, the deadline for submitting comments on the revised draft guidance.

III. CONCLUSION

For the reasons explained above, your Petition is denied.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
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Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research