FDA Staff:

On behalf of the American Association of Naturopathic Physicians (AANP), we appreciate the opportunity to comment on the above-referenced docket with regard to the Agency’s approach to the regulation of homeopathic products. We have reviewed the comments and Citizens Petition prepared by Americans for Homeopathic Choice (AHC), and we join them in their comments, request for relief and proposed approach to the regulation of homeopathic products. We urge the FDA to take into consideration the well-reasoned and balanced approach offered by AHC, which is based both on a comprehensive review of the legal status of homeopathic products and a deep knowledge of homeopathic practice.

AANP is a national professional association (https://www.naturopathic.org) representing 8,000 licensed naturopathic physicians in the United States. Its members are physicians trained as experts in natural medicine. Currently, 25 states and territories license NDs to practice. Naturopathic doctors (NDs) are extensively trained in pharmacology, perform physical examinations, take comprehensive health histories, order lab tests, imaging procedures and other diagnostic tests and treat illnesses. NDs attend four-year, residential graduate level programs at naturopathic medical schools accredited by institutions by the US Department of Education. There are currently seven such schools in North America. Unlike any other profession, ND’s comprehensive foundational coursework includes the practice of homeopathy. As such, we have both unusual expertise in these methods and we and our patients are directly affected by the manner in which FDA chooses to regulate the field.

We note that the proposed guidance does not recognize or address the professional use of homeopathy but is focused on the wide availability of remedies on an OTC basis. The Proposed Guidance notes as a principal basis for the need for an updated regulatory approach that “[i]n the past, these products were mostly prepared by homeopathic physicians for individual patients. Today they are frequently mass manufactured and widely marketed as over the-counter (OTC) products.” Guidance at page 2, lines 55-57. While ND’s frequently use remedies that are commercially available, the essential aspect of physician guided use of remedies remains a central form of therapy which, despite this raison d’être for the guidance, is not considered by FDA.
Some of the suggested enforcement priorities have less application where a professional is involved in care. The guidance that action may be taken against products intended for the prevention or treatment of serious and/or life-threatening diseases or conditions, or for use with vulnerable populations, is based upon OTC sales and is of far less concern when a trained health professional is working up the patient. We ask that FDA guidance be modified to state that this guidance does not apply to the professional use of homeopathy. Similarly, the concern that products that contain or purport to contain ingredients associated with potentially significant safety concerns, particularly for prescription-based items is not the same where under professional supervision. In particular, we would not want to ensure that supplies for professional use are not interrupted over concerns about OTC sales.

We are also concerned about the guidance language with regard to routes of administration other than topical or oral. Given that the vast majority of remedies are entirely benign, use in IM, subcutaneous or even intravenous routes may be clinically useful and reasonable. The likelihood that such routes would pose risk if they have been prepared in sterile, cGMP conditions and used according the training of naturopathic physicians is minimal and can be responsibly assessed given the training of naturopathic physicians.

We appreciate you taking our concerns into account and are available to discuss these matters.

Sincerely,

Alan Dumoff
Counsel