Physicians' Association for Anthroposophic Medicine

219 Hungry Hollow Road, Spring Valley, NY 10977
PO Box 4039, Grand Junction, CO 81502
Fax: 866.334.0243
www.AnthroposophicMedicine.org
paam@anthroposophy.org

Board of Directors

President
Steven Johnson, DO
241 Hungry Hollow Road
Spring Valley, NY 10977

Treasurer
Paul Barratt, MD
481 Kingstown Road
Wakefield, RI 02879

Secretary
Renee Meyer, MD
4277 Hwy 165
Yonges Island, SC 29449

Ricardo Bartelme, MD
1120 Brooks Street
Ann Arbor, MI 48103

Adam Blanning, MD
840 26th Street
Denver, CO 80205

David Gershan, MD
534 Baker Street
San Francisco, CA 94117

Patricia Hart, MD
571 S Allen Road
Flat Rock, NC 28731

Carmen Hering, DO
902 Santa Fe Avenue
Albany, CA 94706

Raphael Knauf, MD
1784 Fairview Road
Glenmoore, PA 19343

John Takacs, DO
5909 SE Division
Portland, OR 97206

August 16, 2018
Docket number: FDA-2018-P-2962-0001

To the Food and Drug Administration:

We have recently been informed of the FDA's publication of the Citizens' Petition by Americans for Homeopathy Choice, dated 7/25/2018 ("Citizens' Petition"). While we did not have any role in the wording of the petition, we nevertheless agree and support the petition's main points and strongly urge that the FDA implement their sensible recommendations.

Specifically, we strongly support that:

1. The FDA establish an expert advisory committee on homeopathy. We have previously recommended this in our letter to the FDA on 3.2.2018. We also feel the FDA should include an additional member on the advisory board who is a licensed physician-expert in anthroposophic medicine. Anthroposophic medicine uses both homeopathic and herbal remedies, other non-pharmacologic modalities, and conventional medicine as part of its holistic therapeutic approach. An expert advisory committee, with the addition of an anthroposophic medical physician, would give the FDA the added expertise it needs to fairly, objectively, and knowledgeably fulfill its legal obligation in the regulation of homeopathic products. As stated in our previous letter, we would be happy to provide a list of names to fill this membership slot.

2. The FDA convert the slightly modified CPG 400.400 found in section C of the petition into a regulation. This would provide sufficient freedom for people to choose homeopathic products, insure their proper safety and eliminate the uncertainty practitioners and manufacturers have when a policy can easily change. The proposed FDA's "Draft Guidance" of December 2017 is flawed in its reasoning, inappropriate, and leaves too much discretion to FDA staff and agents.

3. The FDA withdraw its currently pending guidance document, "Drug Products labeled as Homeopathic: Guidance to FDA Staff and Industry", issued

12.20.2017. We agree with the analysis of this document by Americans for Homeopathy Choice and support its withdrawal.

4. The FDA continue to use the CPG 400.400 as the guiding document for homeopathy until such time as the Citizens' Petition is resolved.

5. The FDA, if it fails to grant the Citizens' Petition requests, hold a public hearing on the matter before enacting the December 2017 Draft Guidance.

In addition to the above, we feel the research in homeopathy that is extensively documented in the Carstens-Stiftung database (see reference 64 in Citizens' Petition) gives abundant evidence from many different studies supporting the safety of homeopathic products for vulnerable ("high risk") populations, including infants, children, pregnant women and their fetuses, and the elderly. Furthermore, the clinical experience of many practitioners, their patients, as well as the FDA's own monitoring, all provide additional evidence to homeopathy's safety. This is in very strong contrast to the published literature and the FDA's own experience with adverse drug reactions with conventional, FDA-approved medical products.

Respectfully submitted,

Physicians' Association for Anthroposophic Medicine (PAAM) Board

Steven Johnson, D.O, President of PAAM
Adam Blanning, M.D.
Ricardo Bartelme, M.D.
David Gershan, M.D.
Patricia Hart, M.D.
John Takacs, D.O.
Renee Meyer, M.D.