March 31, 2015

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
1240 Parklawn Drive
Rockville, MD 20857

Citizens Petition FDA-2013-P-1378
Re: CPG 400.400, Conditions Under Which Homeopathic Drugs May Be Marketed

Dear Sir or Madam:

SUPPLEMENT TO CITIZEN PETITION

The undersigned submitted the referenced petition in accordance with 21 CFR 10.30 on October 10, 2013 requesting that the Commissioner of Food and Drugs revise and reissue FDA Compliance Policy Guide (CPG) 400.400 (formerly numbered 7132.15), "Conditions Under Which Homeopathic Drugs May Be Marketed" and to consider rulemakings that would clearly set forth the criteria for bringing Homeopathic drugs to market, and the marketing of such drugs, in accordance with procedures established by the Food and Drug Administration.

My petition stated that CPG 400.400, which was last revised in 1995, should 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. Further, I urged that FDA work with the National Institute of Health's National Center for Complementary and Alternative Medicines (NCCAM), now renamed the National Center for Complementary and Integrative Health (NCCIH), and others as appropriate, to assist consumers in making informed decisions regarding using such drug products in self-treatment.

Needless to say, I was more than pleased to see FDA's March 26, 2015 announcement that the agency would be holding a Public Hearing on April 20-21 to seek information in an effort to evaluate the agency's framework for Homeopathic Product regulation. I hope my petition helped stimulate this action. In the 16 months since submitting the petition, I have provided consulting services to a number of companies who were marketing or considering the marketing of homeopathic drugs and have participated in several training courses concerning the labeling and marketing of OTC drugs, including Homeopathic drugs. These endeavors have simply reinforced the views I expressed in my October 2013 petition.

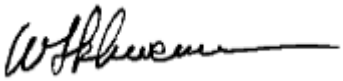
In general, I have found that individuals and companies interested in marketing Homeopathic Drugs fall into essentially two categories. One consists of persons (often with a background in homeopathy or naturopathy) who believe that homeopathic remedies have value in treating certain ailments or conditions of the body. The other category includes those who are generally aware that FDA does not wish to use in resources in dealing with low risk violations and see this as an opportunity to scam the public. The latter are usually aware of some obscure study or article that could be the

foundation of a drug claim, or think that simply labeling an OTC drug as "Homeopathic" will not trigger FDA's review of a product's compliance with an OTC drug Monograph or Tentative Final Monograph.

Just within the past week or two, I observed nationwide TV Advertisements for a product named Cold-EZZE, which was represented as being "Homeopathic." I have no business relationship with the marketer of the product; however, out of curiousity, I googled the product name to see what I could learn. A promotional piece on the promoter's website said, "Cold-EEZE® is a homeopathic cold remedy made with a unique zinc gluconate formula. The active ingredient is listed on a label I found on the NIH dailymed website as "Zincum Gluconium (2x) 13.3 mg". The principal display panel does not say the product is homeopathic and the label includes a drug facts panel as it would for a drug that conforms to a Monograph. Would FDA consider this product to be a conventional drug if the active ingredient were declared as Zinc Glutamate 13.3 mg? The internet revealed that the public is debating the safety and effectiveness of this product as a cold remedy and a similar product sold under the proprietary name "Zicam®." What I did not find on the internet was any clue as to what FDA's view is regarding the safety and/or effectiveness of either drug when taken orally.

During the past year, a client asked me to review a label for a homeopathic product claiming ingredient potencies at 200k. I checked the HPUS website and found no such potency for an ingredient listed or discussed there. After further research on the internet I found that in some parts of Europe the "centesimal series can be labeled as 200k, 1000ck, 1000ck or 1M." Conducting additional research on 200k potencies led me to a December 2006 paper* titled, "Homeopathic Potencies Identified By A New Magnetic Resonance Method: Homeopathy' "An Energetic Medicine." The author of that paper claims,"According to these results, homeopathy has been put on a fundamental, scientific, physical basis."

I bring the matters in the above two paragraphs to the agency's attention only because they illustrate the mass media promotion of certain homeopathic remedies and they provide examples of related information concerning homeopathics that is available to the general public. Such information, in my judgment, makes it virtually impossible for an average person to distinguish between science and pseudoscience, and between drugs whose safety and effectiveness has been established by scientific evidence and those that are simply health fraud.



William L. Schwemer
[redacted]

* http://hpathy.com/scientific-research/homeopathic-potencies-identified-by-a-new-magnetic-resonance-method-homeopathy-an-energetic-medicine/