LAW OFFICE OF ALVIN J. LORMAN

1629 K STREET, NW, SUITE 300 ▪ WASHINGTON, DC 20006
PHONE/FAX: 202.263.1100 ▪ AJL@LORMANLAWDC.COM
WWW.LORMANLAWDC.COM

MEMORANDUM

ATTORNEY-CLIENT PRIVILEGED

TO: American Association of Homeopathic Pharmacists

DATE: June 29, 2020

RE: FDA Warning Letters

The Food and Drug Administration (FDA) has issued a number of Warning Letters to manufacturers and distributors of homeopathic drugs in the past few months.

A number of these letters were sent to companies making Covid-19 claims. Given that Covid-19 is a public health emergency, these Warning Letters should come as no surprise. In addition, even were the products otherwise legitimate, they were all sold OTC for a prescription-only indication. In February, 2020, the AAHP issued a statement that warned that it was "unaware of any homeopathic literature or clinical trial that specifically support the use of any homeopathic drug for prevention or treatment on the emerging 2019 Novel Coronavirus and does not recommend its use in treating 2019-nCoV." That statement was shared with FDA.

More recently, and potentially more troubling, FDA issued in June four Warning Letters to manufacturers or distributors of injectable homeopathic products. The FDA issued the June, 2020 Warning Letters to Hevert Pharmaceuticals, LLC; MediNatura, Inc.; 8046255 Canada, Inc., doing business as Viatrexx; and World Health Advanced Technologies, Ltd. FDA said that, "The products included in the warning letters are new drugs because they are not generally recognized as safe and effective for their labeled uses, and FDA has not approved these products." In a press release, FDA said that it was acting because "the lack of premarket quality review is particularly concerning for injectable drugs, which generally pose a greater risk of harm to users because the route of administration for these products bypasses some of the body's natural defenses."

The charge that the products are unapproved new drugs is consistent with FDA's long-standing position that homeopathic drugs are not exempt from the pre-market approval process of the Federal Food, Drug, and Cosmetic Act. Despite FDA's claimed safety concerns, it appears that the products sold by the two AAHP member companies have a low or non-existent

number of serious adverse event reports and FDA cited no specific dangers. (The AAHP has no information on the adverse event reports, if any, of the other two companies.) All were sold by prescription only. The Canadian company was also cited for various cGMP issues. Although the Warning Letters afforded the recipients 15 days in which to respond, FDA added the imported injectables to the Import Alert list on the day the Warning Letters were issued. FDA's press release, with links to the Warning Letters, is available at https://www.fda.gov/news-events/press-announcements/fda-warns-four-manufacturers-unapproved-injectable-drugs-labeled-homeopathic

FDA's revised draft guidance on homeopathic products lists route of administration as one of the agency's enforcement priorities. Because of concern that FDA was simply going to go down the list of its stated priorities and remove categories of homeopathic drugs from the market, AAHP President Mark Land arranged a video conference with Don Ashley, Director of CDER's Office of Compliance. Ashley told Land that the action against the homeopathic injectable products was consistent with similar actions taken against other categories of injectable products which lacked FDA pre-market approval.

Finally, an AAHP member has received an extensive Warning Letter based largely on perceived cGMP deficiencies.

The association is continuing to monitor these efforts and afford member companies appropriate assistance.