DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JUN 5 2014

William L. Schwemer
289 Morningwood Lane
Wirtz, Virginia 24184

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

Dear Mr. Schwemer:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 24, 2013. Your petition requests that the Agency revise and reissue FDA compliance policy guide (CPG) 400.400 and to consider rulemakings that would clearly set forth the criteria for bringing homeopathic drugs to market and the marketing of such drugs.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research