U.S. FOOD & DRUG ADMINISTRATION

Sidney M. Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009

Re: Docket No. FDA-2017-P-6758

JUN - 4 2018

Dear Dr. Wolfe:

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 December 6, 2017. Your petition requests that the Agency: (1) immediately add cesium chloride to the list of bulk drug substances that raise significant safety risks and therefore may not be included in compounded drug products, as described in the Agency's 2017 Guidance for Industry entitled "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act;" and (2) promulgate a rule that excludes cesium chloride from the list of bulk drug substances that can be used to compound drug products under section 503A of the Federal Food, Drug, and Cosmetic Act.

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,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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