DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 6, 2017

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

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug immediately add cesium chloride to the list of bulk drug substances that raise significant safety risks (the 503A Category 2 list) and therefore may not be compounded under the Agency's January 2017 Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act – Guidance for Industry and promulgate a rule that excludes cesium chloride from the list of bulk drug substances that although they are neither the subject of an applicable USP or NF monograph nor components of FDA-approved drugs, can be used to compound drug products under section 503A of the FDCA was received by this office on 12/6/2017.

It was assigned docket number FDA-2017-P-6758. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)