



December 19, 2018

Michael A. Carome, M.D.
Meena M. Aladdin, M.S. Ph.D.
Health Research Group
Public Citizen
1600 20th Street, NW
Washington DC 20009

Dear Drs. Aladdin and Carome:

This is to acknowledge receipt of your letter dated October 9, 2018. We thank you for bringing this information to our attention. FDA has reviewed the information that you provided concerning cesium chloride. As you are aware, FDA identified significant safety risks relating to the use of cesium chloride in compounding and placed cesium chloride in 503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks. If FDA encounters a compounder using a substance in category 2, the FDA intends to take regulatory action, such as issuing a warning letter or seizing product.

Please note, the agency generally does not comment on specific activities of individuals or companies, except to the involved entity.

Should you have any questions regarding compounding or would like to forward additional information, please write to compounding@fda.hhs.gov.

Sincerely,

Compounding and Pharmacy Practices Branch
Division of Prescription Drugs
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration