IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, INC., and PUBLIC CITIZEN'S HEALTH RESEARCH GROUP, 1600 20th Street NW Washington, DC 20009, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	)	Civil Action No. 19-2701

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs Public Citizen and Public Citizen's Health Research Group (collectively, Public Citizen) bring this action pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 and 706, to compel the Food and Drug Administration (FDA) to act on Public Citizen's petition requesting that the FDA require the removal from the market of all dietary supplements containing cesium chloride or any other cesium salt. In that petition, Public Citizen specifically requested that the FDA take the following actions: (1) immediately issue a determination that dietary supplements containing cesium chloride or any other cesium salt present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use and require that all such dietary supplements be removed from the market; and (2) issue an FDA safety

communication advising consumers and health care professionals about the harms that can result from supplementation with cesium chloride or any other cesium salt.

2. On July 23, 2018, Public Citizen petitioned the FDA to take these actions. In support of its petition, Public Citizen cited substantial scientific evidence demonstrating that cesium chloride poses significant health risks. The FDA acknowledged these health risks on the same day Public Citizen filed its petition. That day, the FDA issued a risk alert concluding that "[t]he use of cesium poses significant safety risks (e.g., heart toxicity) and is potentially associated with death," and took action to block use of cesium chloride in drug compounding. FDA, *FDA alerts health care professionals of significant safety risks associated with cesium chloride* (July 23, 2018), https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-professionals-significant-safety-risks-associated-cesium-chloride (FDA Alert).

3. Despite the FDA's recognition of the dangers posed by cesium chloride, more than a year has passed since Public Citizen submitted its petition, and the FDA has neither granted nor denied the petition. To protect public safety and forestall preventable death and injury, Public Citizen seeks a declaration that the FDA has acted unlawfully by withholding action on Public Citizen's petition and an order requiring the FDA to act on the petition.

PARTIES

4. Plaintiff Public Citizen, Inc., a non-profit, public-interest research, litigation, and advocacy organization based in Washington, D.C., advocates before Congress, regulatory agencies, and in the courts to advance the interests of its members on a wide range of consumer-protection issues. Plaintiff Public Citizen's Health Research Group (HRG) promotes research-based, system-wide changes in health care policy and provides oversight concerning drugs,

medical devices, dietary supplements, doctors, hospitals, and occupational health. Public Citizen and HRG submitted the citizen petition at issue in this suit.

5. Defendant FDA is a component of the Department of Health and Human Services, an agency of the federal government. The FDA is responsible for administration of the FDCA. In particular, the FDA is responsible for regulating dietary supplements as adulterated foods when they "present[] a significant or unreasonable risk of illness or injury under … conditions of use recommended or suggested in labeling, or … if no conditions of use are suggested or recommended in the labeling, under ordinary use." 21 U.S.C. § 342(f)(1)(A).

JURISDICTION

6. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

Regulatory Background

7. The FDCA grants the FDA supervisory authority over food, drugs, and dietary supplements. *See* 21 U.S.C. §§ 301 *et seq.* In 1994, Congress amended the FDCA with the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (DSHEA). Among other provisions, DSHEA amended section 402 of the FDCA, 21 U.S.C. § 342, to define as an "adulterated food" any "dietary supplement" that "presents a significant or unreasonable risk of illness or injury under—(i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A). Under 21 U.S.C. § 331(a), the "introduction or delivery for introduction into interstate commerce of any" such adulterated food is prohibited.

Cesium Chloride

8. Cesium is an alkali earth metal that has chemical properties similar to lithium, sodium, and potassium and that exists as a trace element in human metabolism. When taken orally,

cesium chloride is nearly 100 percent absorbed in the small intestine, and kinetic modeling suggests that cesium distribution is extensive—with especially high concentrations in the kidneys, skeletal muscle, liver, red blood cells, and brain.

9. Cesium compounds have long been promoted without FDA approval by doctors and cancer centers as an alternative treatment of cancer known as "high pH therapy." However, as an FDA clinical review noted, "Cesium chloride has not been shown to be efficacious for the prevention or treatment of any form of cancer." The only evidence of "clinical benefit from cesium in human cancer" is limited to one 1984 study with "major flaws including its uncontrolled nature, retrospective design and probable case selection bias." FDA, *FDA Briefing Document: Pharmacy Compounding Advisory Committee (PCAC) Meeting, June 23, 2016*, at Tab 2b, p. 7, https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf (FDA Briefing Document).

10. Moreover, a growing body of evidence demonstrates that cesium chloride or other cesium salt supplementation can cause serious, life-threatening, adverse cardiovascular events when taken in amounts recommended or suggested in product labeling, or, if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use.

The FDA's Recognition of Cesium Chloride's Risks and Action on Cesium Chloride and Drug Compounding

11. In a May 2016 evaluation of cesium chloride for the purpose of considering whether the substance could be used in pharmacy compounding, FDA reviewers flagged "serious safety concerns related to the use of cesium chloride." The reviewers noted that "[n]on-clinical studies show significant cardiac and central nervous system toxicity including ventricular tachycardia, decreased motor activities, and autonomic disturbances." In addition, "[c]linically, numerous reports of serious toxicity following cesium chloride use for the treatment of cancer have been

made with effects including hypokalemia seizures, ventricular arrhythmias, syncope, and death." The reviewers concluded that "[c]esium chloride is not safe for human use and there is no evidence it is effective for the treatment of any cancer. Relying on this type of treatment may have serious health consequences, including ventricular arrhythmias and cardiac arrest." FDA Briefing Document, at Tab 2b, p. 9.

12. On December 6, 2017, Public Citizen submitted a citizen petition to the FDA asking the FDA, among other things, to immediately add cesium chloride to the category of bulk drug substances that present significant safety risks and therefore may not be compounded under interim guidance issued by the FDA in 2017.

13. On July 23, 2018, the FDA responded to Public Citizen's compound-drugs petition, granting the petition to the extent it asked the FDA to add cesium chloride to the category of bulk drug substances that present significant safety risks and therefore may not be used in compounding under the FDA's 2017 interim guidance. *See* Letter from Janet Woodcock, FDA, to Sidney M. Wolfe, HRG (July 23, 2018), *available at* https://www.regulations.gov/document?D=FDA-2017-P-6758-0004.

14. In its response, the FDA stated that it had "recently conducted a comprehensive review of the FDA Adverse Events Reporting System (FAERS), Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS), and medical literature for all adverse events related to cesium chloride and other cesium salts through June 30, 2018," and that its "current findings support [its] previous conclusions" about the safety risks posed by cesium chloride. The FDA noted that "[s]ince 2016, there have been three more published case reports related to cesium chloride that describe life-threatening neurologic and cardiac toxicity," which further increased the FDA's "concern about the risks of cesium chloride." The FDA

concluded that the "available data indicate that the use of cesium chloride is associated with serious adverse events and potentially associated with fatalities." *Id.* at 5.

15. That same day, the FDA issued an alert for health care professionals warning that "use of cesium poses significant safety risks (e.g., heart toxicity) and is potentially associated with death." FDA Alert.

16. On September 5, 2019, the FDA issued a proposed rule to exclude cesium chloride from the FDA's list of bulk drug substances that can be used to compound drug products under section 503A of the FDCA. In the proposed rule, the FDA stated: "Both nonclinical and clinical studies give rise to significant safety concerns related to the use of cesium chloride in compounded drug products. Those concerns include links between cesium chloride use and hypokalemia, seizures, QT prolongation, and cardiac arrhythmias. There is no evidence that cesium chloride would be effective in the prevention or treatment of cancer." FDA, *Amendments to the List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act*, 84 Fed. Reg. 46688, 46695 (Sept. 5, 2019).

Public Citizen's Citizen Petition Concerning Use of Cesium Chloride in Dietary Supplements

17. Despite the FDA's recognition of the risks associated with cesium chloride and the steps the FDA has taken against the use of cesium chloride in pharmacy compounding, the substance remains readily available to consumers through dietary supplements and is marketed, in particular, to cancer patients.

18. On July 23, 2018, pursuant to 21 C.F.R. § 10.30, Public Citizen submitted to the FDA a citizen petition asking the FDA to (1) immediately issue a determination that dietary supplements containing cesium chloride or any other cesium salt present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the

labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use and require that all such dietary supplements be removed from the market; and (2) issue an FDA safety communication advising consumers and health care professionals about the harms that can result from supplementation with cesium chloride or any other cesium salt.

19. Public Citizen's petition provides sufficient grounds for the FDA to take the actions that Public Citizen requested. For instance, the petition addresses the marketing of cesium chloride supplements, previous FDA conclusions about cesium toxicity, and the evidence of cardiac toxicity and adverse central nervous systems effects of cesium chloride.

20. On January 30, 2019, the FDA provided an interim response to Public Citizen's petition. The FDA stated that it had not reached a decision on the petition "due to competing agency priorities."

21. To date, the FDA has not issued a decision on Public Citizen's petition or taken the actions that Public Citizen requested to prevent the use of cesium chloride in dietary supplements.

22. The considerable danger to public health occasioned by the FDA's failure to act on Public Citizen's petition counsels in favor of expeditious action. The FDA's decisional process is lagging unreasonably in light of the nature and extent of the public health interests addressed in the petition.

CLAIM FOR RELIEF

23. Public Citizen is entitled to a decision on its citizen petition. *See* 21 C.F.R. § 10.30(e)(1).

24. The FDA's failure to act on Public Citizen's petition constitutes agency action unlawfully withheld or unreasonably delayed under the APA. 5 U.S.C. § 706(1).

25. The FDA's failure to act on Public Citizen's petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A).

WHEREFORE, Plaintiff requests that this Court

A. Declare unlawful the FDA's failure to act on Public Citizen's petition;

B. Order the FDA to issue a decision on Public Citizen's petition within 30 days of the Court's order;

C. Award Public Citizen its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted

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