IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, 1600 20th Street NW Washington, DC 20009, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	)	Civil Action No. 20-2385

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Public Citizen brings 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 United States Food and Drug Administration (FDA) to act on a petition Public Citizen filed on July 7, 2015, regarding Seprafilm Bioresorbable Membrane (Seprafilm), an anti-adhesion barrier device used in abdominal and pelvic surgical procedures. In that petition, Public Citizen requested that the FDA withdraw approval of and initiate a mandatory recall of Seprafilm, because the medical device's manufacturer has not demonstrated reasonable assurance that the device is safe and effective under its current conditions of use and there is a reasonable probability that the device will cause serious adverse health consequences and death.

2. Although more than five years have passed since Public Citizen filed its petition, the FDA has neither granted nor denied the petition. In this action, 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 thereon.

PARTIES

3. Plaintiff Public Citizen is a non-profit, public-interest research, litigation, and advocacy organization based in Washington, D.C. Since its founding in 1971, Public Citizen has advocated before Congress, regulatory agencies, and in the courts to advance the interests of its members on a wide range of consumer-protection issues, including issues related to drugs, medical devices, and health care policy. Public Citizen submitted the petition at issue in this case.

4. 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 approving new medical devices and for withdrawing and recalling medical devices when warranted. *See* 21 C.F.R. Parts 810 & 814.

JURISDICTION

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

FACTS

6. Seprafilm is an anti-adhesion barrier device. The device is a bioresorbable membrane that adheres to tissue surfaces and hydrates to form a viscous gel coating. Seprafilm is used in abdominal and pelvic surgical procedures to prevent the formation of postoperative adhesions (fibrous bands that form between tissues and organs).

7. The FDA approved the Seprafilm premarket approval application in 1996. Seprafilm's sponsor, Genzyme, submitted to the FDA data from three randomized, controlled clinical trials to support the efficacy claims in the Seprafilm label: HF92-0901 (Study 901) and HF92-0902 (Study 902), which were conducted prior to approval of the original premarket

approval application, and SF97-0601(Study 601), which was conducted afterwards. None of these studies established the product's efficacy in improving any important clinically meaningful outcomes.

8. Moreover, two of the studies—Studies 901 and 601—raised serious safety concerns. In Study 901, although the overall rates of adverse events were similar in Seprafilm and control-group subjects, subjects assigned to the Seprafilm group experienced a higher rate of serious adverse events than control subjects. In Study 601, subjects randomized to the Seprafilm group were significantly more likely to experience anastomotic leak, peritonitis, vomiting, and fistula relative to those randomized to the control group.

9. Data from several nonrandomized studies have also raised serious concerns about Seprafilm's safety. For example, a retrospective review of a consecutive series of 375 patients undergoing laparotomies for cytoreductive surgery for ovarian, fallopian tube, or peritoneal cancer between January 1995 and December 2008 at The Johns Hopkins Medical Institutions found a significantly increased risk of pelvic abscess in the Seprafilm cohort compared to the non-Seprafilm cohort.

10. In addition, there are numerous case reports in the scientific medical literature of adverse events associated with the use of Seprafilm during abdominal or pelvic surgery, and several case reports of patients undergoing surgery with Seprafilm who, within several days postoperatively, developed signs of severe acute inflammatory reactions. In some cases, symptoms resolved after the abdominal cavity was thoroughly irrigated and the Seprafilm residue completely removed.

11. As of July 7, 2015, Public Citizen was aware of at least 21 reports in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database of deaths in patients who

underwent surgery with placement of Seprafilm. The catastrophic events described in these reports included acute respiratory distress syndrome, peritonitis, and overwhelming sepsis. Since then, two additional reports of patient deaths associated with use of Seprafilm have been submitted to the MAUDE database. One of these most recent cases involved a fatal allergic fibrotic reaction within the abdominal cavity.

12. In addition to death reports, Public Citizen identified 524 MAUDE database reports between January 1, 1998, and May 27, 2015, of adverse events linked to the brand name Seprafilm. Among the adverse events cited in numerous MAUDE reports for Seprafilm were bowel obstruction, abscess, peritonitis, fever, fluid collection, inflammatory reaction, leak, fistula, sepsis, and wound dehiscence. A number of MAUDE reports described the formation of adhesions, fibrous tissue formation, inflammatory reactions, or other problems precisely where the Seprafilm had been placed and, in some cases, with a geometric size and shape corresponding to a sheet of Seprafilm. In other cases, it appeared that the Seprafilm did not fully dissolve as intended, and instead persisted in gel or film form. Since July 2015, more than 100 additional reports of adverse events linked to use of Seprafilm have been reported to the MAUDE database.

13. On July 7, 2015, pursuant to 21 C.F.R. § 10.30, Public Citizen sent a petition to the FDA urging the FDA to withdraw the premarket approval of Seprafilm and to initiate a mandatory recall of all remaining unused Seprafilm devices on the grounds that the manufacturer has not demonstrated reasonable assurance that the device is safe and effective under its current conditions of use and there is a reasonable probability that the device will cause serious adverse health consequences and death. In its petition, Public Citizen discussed data from randomized controlled clinical trials, nonrandomized clinical trials, case reports, and MAUDE data, and noted the additional risks posed by off-label uses of Seprafilm. The petition explained that "clinical trials of

Seprafilm failed to demonstrate convincingly the product's efficacy in improving any important clinically meaningful endpoint" and "there is substantial evidence that the product causes serious, sometimes fatal adverse events."

14. Public Citizen's petition provided sufficient grounds for the FDA to withdraw the premarket approval of Seprafilm and to initiate a mandatory recall of all remaining unused Seprafilm devices.

15. The day Public Citizen submitted its petition, the FDA docket management division acknowledged its receipt of the petition and assigned it docket number FDA-2015-P-2375.

16. On October 6, 2015, the FDA sent a letter to Public Citizen, indicating that the FDA had not yet reached a decision on the petition because the petition "raises issues requiring further review and analysis by Agency officials."

17. To date, the FDA has not issued a decision on Public Citizen's petition or taken either of the actions requested in the petition. The FDA has failed to act despite the seriousness of the safety risks posed by Seprafilm.

18. The FDA's decisional process is lagging unreasonably in light of the nature and extent of the public health interests addressed in the petition.

CLAIMS FOR RELIEF

20. The FDA's failure to act on Public Citizen's petition constitutes agency action unlawfully withheld or unreasonably delayed and violates the Administrative Procedure Act, 5 U.S.C. § 706(1).

21. 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 and violates the Administrative Procedure Act, 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,

/s/ Adina H. Rosenbaum
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