IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MICHAEL WEBER
183 Beech Street
Eastchester, NY 10709

Plaintiff,

v. C.A. No. _____

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20854

Defendant.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Michael Weber 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 Mr. Weber's June 2, 2008, citizen petition requesting the FDA to exclude the use of wheat gluten as an inactive ingredient or excipient in both prescription and over-the-counter (OTC) drugs or, in the alternative, to impose new labeling requirements for medications containing wheat gluten. Mr. Weber's petition noted that approximately one percent of the U.S. population suffers from celiac disease, that those people experience severe health problems when exposed to wheat gluten, that there is a lack of labeling and tracking mechanisms for medications that contain wheat gluten, and that pharmaceutical manufacturers can easily substitute other excipients for wheat gluten. Although nearly seven years have passed since Mr. Weber filed his petition, the FDA has neither granted nor denied the petition, and has taken no action to ban the

use of gluten in pharmaceuticals or to require additional labeling. Therefore, Mr. Weber seeks a declaration that the FDA has acted unlawfully by withholding action on his petition and an order requiring the FDA to act thereon.

PARTIES

2. Plaintiff Michael Weber resides in Eastchester, New York, and suffers from celiac disease.

3. Defendant FDA is an agency within the United States Department of Health and Human Services (HHS). By delegation from HHS, the FDA is responsible for administration of the FDCA. In particular, the FDA is responsible for withdrawing approval of unsafe drugs, *see* 21 U.S.C. § 355(e), for determining which inactive ingredients are safe, *see, e.g.*, 21 C.F.R. § 330.1(e), and for regulating the content and format of drug labeling, *id*. § 201.

JURISDICTION

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

FACTS

Background

5. Gluten is a protein found in wheat, barley, and rye. Wheat gluten is the principle protein in wheat. 21 C.F.R. § 184.1322(a).

6. Gluten is used as an inactive ingredient in drug products. *See* FDA, Inactive Drug Database, CAS No. 8002800, *available at* http://www.accessdata.fda.gov/scripts/cder/iig/getiigWEB.cfm. Wheat gluten may be used as a filler starch or in the coating of a capsule or tablet. *See* N. Am. Soc'y for Study of Celiac Disease Comment, FDA-2011-N-0842-0029, at 1 ("NASSCD Comment").

7. Celiac disease is an auto-immune disease that affects as many as three million people in the United States or roughly one percent of the population. Nat'l Found. for Celiac Awareness Comment, FDA-2011-N-0842-0039, at 1; FDA, Gluten in Drug Products, Request for Information and Comments, 76 Fed. Reg. 79,196, 79,196 (Dec. 21, 2011). An estimated 3 to 13 children out of 1000 have the disease. *See* Nat'l Ass'n for Pediatric Gastroenterology, Hepatology and Nutrition and Am. Acad. of Pediatrics Comment, FDA-2011-N-0842-0040, at 1 ("NASPGHAN Comment").

8. When a person with celiac disease ingests wheat gluten, his or her body produces an auto-immune response that attacks the small intestine, hindering nutrient absorption. Gluten in Drug Products, 76 Fed. Reg. at 79,196; NASSCD Comment at 1.

9. For children with celiac disease, exposure to wheat gluten can stunt growth and cause abdominal pain, diarrhea, constipation, vomiting, and delayed puberty, among other problems. NASPGHAN Comment at 2.

10. For individuals with celiac disease, prolonged exposure to gluten can cause intestinal cancers, impaired fertility, autoimmune disease, and increased mortality rates. NASSCD Comment at 1.

11. The treatment for celiac disease is adherence to a gluten-free diet. *Id.*; Gluten in Drug Products, 76 Fed. Reg. at 79,196.

12. Recognizing the significant dangers of gluten consumption for people with celiac disease, Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202(6), 118 Stat. 891 (codified as 21 U.S.C. § 343 note), Congress has identified wheat and wheat gluten as "major food allergen[s]" and required labeling to identify food products containing those ingredients, 21 U.S.C. §§ 321(qq), 343(w).

13. Gluten contained in regularly consumed medications can trigger the symptoms of celiac disease. NASSCD Comment at 1.

14. Patients with celiac disease may need to spend significant time and effort to determine whether gluten is contained in the medications they take, a problem made more difficult because brand-name drugs may use different excipients than their generic equivalents, and one generic drug may use different excipients than another generic for the same drug product. *Id.*

15. The FDA has the authority to promulgate regulations to bar the use of gluten in medications. 21 U.S.C. § 371(a); 21 C.F.R. § 314.2.

16. Gluten is considered a "drug" when it is used as a component of a product that is a "drug" under the FDCA, 21 U.S.C. § 321(g)(1)(D), and the FDCA requires the FDA to withdraw approval of unsafe drugs, *id.* § 355(e).

17. The FDA deems an OTC drug safe and not misbranded if it "contains only suitable inactive ingredients [that] are safe in the amounts administered." 21 C.F.R. § 330.1(e).

18. The FDA has the authority to require labeling changes to drugs containing gluten. 21 U.S.C. § 355(o)(4); *see id.* § 352(f)(2) (drug is misbranded unless labeling provides "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health").

Mr. Weber's Citizen Petition

19. On June 2, 2008, Mr. Weber petitioned the FDA to eliminate wheat gluten in medications or, in the alternative, to impose new labeling requirements on drugs containing wheat gluten. *See* FDA Docket No. FDA-2008-P-0333-0001. In his petition, he explained the difficulties that he and others with celiac disease face when taking needed medications, including

time-consuming phone calls to pharmacists and pharmaceutical manufacturers, internet searches, and accidental gluten exposure. *Id.* at 5-6.

20. On June 2, 2008, the FDA accepted Mr. Weber's petition for filing. FDA-2008-P-0333-0002. The FDA posted the petition on www.regulations.gov, which states that 73 comments were filed in connection with the petition and makes available 22 of the comments—all supportive of Mr. Weber's petition.

21. On November 18, 2008, the FDA informed Mr. Weber by letter that the "FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." FDA-2008-P-0333-0003.

22. Over a year later, on April 8, 2010, Mr. Weber wrote to the FDA seeking an update on the status of his petition, and on May 10, 2010, the FDA responded that his petition "remain[ed] under review." FDA-2008-P-0333-0024.

23. To assist with evaluating Mr. Weber's petition, the FDA published a Request for Information and Comments concerning "Gluten in Drug Products," on December 21, 2011. 76 Fed. Reg. at 79,196; *see also* FDA-2008-P-0333-0027. According to www.regulations.gov, the FDA received 138 comments in response to the Request during the comment period, which closed in March 2012. *See* FDA Docket No. FDA-2011-N-0842-0001. Several medical and celiac-disease associations including the North American Society for the Study of Celiac Disease, FDA-2011-N-0842-0029; the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition, FDA-2011-N-0842-0040; the American Academy of Pediatrics, *id.*; the Celiac Sprue Association, FDA-2011-N-0842-0045; the American Gastroenterological Association, FDA-2011-N-0842-0041; and the National Foundation for Celiac Awareness, FDA-2011-N-0842-0039, provided comments supporting a ban on gluten in medications. Two

associations supporting manufacturing interests, the International Pharmaceutical Excipients Council of the Americas, FDA-2011-N-0842-0042, and the Consumer Healthcare Products Association, FDA-2011-N-0842-0043, provided comments stating a preference for a labeling rule, rather than a ban.

24. On June 2, 2014, Mr. Weber wrote to the FDA seeking a further status update on his petition and an explanation for the FDA's delay. On July 9, 2014, FDA responded by letter, indicating that it would "respond as soon as we have reached a decision on your request." FDA-2008-P-0333-0027.

25. To date, the FDA has not issued a decision on Michael Weber's petition and has taken no action to ban wheat gluten from drugs or to require labeling.

26. Nearly seven years have passed since Mr. Weber filed his petition, and three years have passed since the comment period closed on the FDA's related Request for Information. The FDA's delay is unreasonable in light of the nature and extent of the public health interests implicated by the citizen petition. Without FDA action on Mr. Weber's petition to ban pharmaceuticals containing wheat gluten or to require labeling of drug products containing wheat gluten, Mr. Weber and the millions of Americans who suffer from celiac disease will continue to experience or risk injury from medications that contain wheat gluten.

CLAIMS FOR RELIEF

27. The FDA's failure to act on Michael Weber's petition for nearly seven years constitutes agency action unlawfully withheld or unreasonably delayed, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1).

28. The FDA's failure to act on Mr. Weber's petition is not in accordance with law and violates the Administrative Procedure Act, *id.* § 706(2)(A).

WHEREFORE, Plaintiff requests that this Court

A. Declare unlawful the FDA's failure to act on Mr. Weber's citizen petition;

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

C. Award Mr. Weber his reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,

/s/ Kathryn Einspanier

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