



August 14, 2024

Marcella Hernandez

(b) (6)

Sent via email to: (b) (6)

Re: Docket Number FDA-2022-P-3257

Dear Ms. Hernandez:

This letter responds to your citizen petition, dated December 17, 2022 (“Petition”), requesting that the Food and Drug Administration (FDA or we) revoke regulations authorizing the use of Per and Polyfluoroalkyl Substances (PFAS) in paper/paperboard packaging for pet food. You request that “this specific application category be revoked due to recent scientific research.” (See Citizen Petition from Marcella Hernandez, sent to the Division of Dockets Management, Food and Drug Administration, dated December 17, 2022, at page 1).

In accordance with 21 CFR 10.30(e)(2)(iii), and for the reasons stated below, we are dismissing your request.

I. Legal Background and Regulatory Framework for Food Additives and Food Contact Substances

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines “food additive,” as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of food, if such substance is not generally recognized by experts as safe under the conditions of its intended use.¹ A food additive is subject to pre-market review and authorization by FDA. A food contact substance is a food additive, and therefore requires premarket authorization. A food contact substance is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.² A food additive is deemed unsafe unless that substance and its use conform with a regulation issued under section 409 of the FD&C Act or unless there is a food contact notification (FCN) submitted under section 409(h) of the FD&C Act that is effective. Section 409(h) of the FD&C Act and our regulations at 21 CFR 170.100 prescribe the procedures for the FCN program.

¹ Section 201(s) of the Federal Food, Drug and Cosmetic Act.

² See section 409(h)(6) of the FD&C Act and 21 C.F.R. § 170.3(e)(3).

Grease-proofing agents authorized by FDA for use on paper or paperboard may potentially migrate to food, which would result in them becoming a component of food and therefore would be considered a food additive under the FD&C Act. Any food additive, including food contact substances, must be shown to be safe for its intended use in accordance with 21 CFR 170.3(i), which defines safety as “a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.” To ensure that a food contact substance, such as one containing PFAS, is safe for its intended use in accordance with 21 CFR 170.3(i), FDA conducts a rigorous review of the available scientific data on the food contact substance prior to authorizing the use.

II. Petition Summary and FDA’s Response

Your citizen petition requests that we revoke the application of PFAS to “pet food bags” under Paper/paperboard food packaging application category (Petition at page 1). Your petition provided a printout of our website dated Dec. 16, 2022, which stated,

PFAS may be used as grease-proofing agents in fast-food wrappers, microwave popcorn bags, take out paperboard containers, and pet food bags to prevent oil and grease from foods from leaking through the packaging.

Our website has since been updated to reflect that grease-proofing agents containing PFAS are no longer marketed for food contact use, including for pet food use, in the United States.³ Because authorized grease-proofing agents containing PFAS are no longer available for sale in the U.S. food contact market, we believe this addresses your concerns about the use of PFAS as a grease-proofing agent in pet food packaging.

As background, FDA revoked applicable regulations and worked with industry to address use of grease-proofing agents that contain PFAS (which were authorized for use under effective food contact notifications). Specifically, in 2011, FDA accepted voluntary commitment letters from the three manufacturers that market food contact substances containing certain long-chain (≥ 8 carbons) PFAS, to cease sales of their grease-proofing agents sold in the U.S. food contact market.⁴ In 2016, FDA revoked the regulations authorizing uses of additional grease-proofing agents containing long-chain PFAS listed in 21 CFR § 176.170.⁵ In July 2020, FDA also accepted voluntary commitment letters from the four manufacturers that market grease-proofing agents containing specific short-chain (typically 6 carbons) PFAS to cease sales of these food contact substances.⁶ One manufacturer ceased sales in 2019, and three others phased out U.S. sales by the end of 2023.⁷ In 2023, FDA also received confirmation from the manufacturers of

³ <https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications>

⁴ See FDA’s website [Authorized Uses of PFAS in Food Contact Applications | FDA](#) for discussion of the Market Phase-out and Revocation of Authorization of Long-Chain PFAS as well as copies of the voluntary commitment letters from BASF Corporation, E.I. Dupont de Nemours & Co., and Clariant Corporation.

⁵ See 81 FR 5 (January 4, 2016) and 81 FR 83672 (November 22, 2016).

⁶ There are no authorizations listed in Title 21 of the Code of Federal Regulations for food contact substances containing short-chain PFAS.

⁷ See FDA’s website [Authorized Uses of PFAS in Food Contact Applications | FDA](#) for discussion of the Market


all remaining authorized grease-proofing substances containing different types of PFAS that those manufacturers had ceased to produce and sell those food contact substances.⁸ As noted in FDA's constituent update issued on February 28, 2024, we received confirmation that all grease-proofing agents containing PFAS are no longer marketed in the United States.⁹

As grease-proofing agents containing PFAS are no longer marketed for food contact use in the United States, we are not specifically addressing the evidence cited in the petition.

III. Conclusion

For the reasons described above, we are dismissing your petition in accordance with 21 CFR 10.30(e)(2)(iii). The facts have changed since your petition was submitted, rendering the petition moot. Based on recent FDA and industry actions, authorized grease-proofing agents containing PFAS are no longer available for sale in the U.S. food contact market. We believe this addresses the concerns raised in your petition about the use of PFAS as a grease-proofing agent in pet food packaging.

Sincerely,

Kristi L. Muldoon Jacobs -S  Digitally signed by Kristi L. Muldoon Jacobs -S
Date: 2024.08.14 15:33:40 -04'00'

Kristi Muldoon Jacobs, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Phase-Out of Certain Short-Chain PFAS as well as copies of the voluntary commitment letters from Archroma Management GmbH, AGC Chemicals Americas, Daikin America, Inc., and the Chemours Company.

⁸ See FDA's website [Market Phase-Out of Grease-Proofing Substances Containing PFAS](#) for discussion of the Notification of Cessation of Sales of Remaining Grease-Proofing Substances Containing PFAS as well as copies of the voluntary commitment letters from Archroma US Inc, Solenis LLC, and Solvay Specialty Polymers USA LLC

⁹ <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-pfas-used-grease-proofing-agents-food-packaging-no-longer-being-sold-us>.