

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York
Attorney for Defendant and
Defendant/Counterclaim Plaintiff
By: ALLISON M. ROVNER
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: 212.637.2691
Fax: 212.637.2750
Email: allison.rovner@usdoj.gov

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TZUMI INNOVATIONS, LLC,
Plaintiff/Counterclaim Defendant,

-v-

MICHAEL S. REGAN,¹ in his Official Capacity as
Administrator of the United States Environmental
Protection Agency,

Defendant,

UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY,

Defendant/Counterclaim Plaintiff.

21 Civ. 0122 (LGS)

**AMENDED ANSWER
WITH
COUNTERCLAIM**

The United States of America (“United States”), on behalf of the U.S. Environmental Protection Agency (“EPA”), by and through its attorney Damian Williams, United States Attorney for the Southern District of New York, on behalf of the Administrator of EPA, hereby incorporates

¹ Michael S. Regan, who became the Administrator of the Environmental Protection Agency on March 11, 2021, is automatically substituted for former Administrator Andrew R. Wheeler as the defendant in this action. *See* Fed. R. Civ. P. 25(d).

by reference its answer filed on August 27, 2021 (ECF No. 60) to the amended complaint (ECF No. 27) and asserts its counterclaim against Plaintiff/Counterclaim Defendant Tzumi Innovations, LLC (“Tzumi”), as follows:

INTRODUCTION

1. At the height of the COVID-19 pandemic—in an admitted effort to capitalize on the increased demand for disinfectant products during the pandemic—Tzumi illegally distributed and sold millions of unregistered antimicrobial household products across the United States, under the “Wipe Out!” brand (the “Wipe Out! Products”). The labeling for these products suggested that they were safe and effective for use as antimicrobial agents on surfaces in homes. To lawfully distribute or sell products making such a claim, however, Tzumi was required to first register the products as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 USC §§ 136 to 136y. It failed to do so, thus evading EPA’s review of whether the Wipe Out! Products were effective and whether they would cause unreasonable adverse effects on human health or the environment. It was illegal for Tzumi to distribute and sell such unregistered pesticides.

2. Compounding matters, although Tzumi’s Wipe Out! Products were sold through national retailers, Tzumi targeted low-income populations as potential consumers. Low-income communities in general bear a disproportionate burden of environmental exposures and public health risks and selling unregistered pesticides to these communities raises particular concerns of environmental justice.

3. EPA brings this counterclaim pursuant to Section 16(c) of FIFRA, 7 U.S.C. § 136n(c), for an order enforcing FIFRA’s requirements with respect to the Wipe Out! Products,

preventing future violations, and providing other appropriate equitable relief, including mitigation of the effects of prior violations.

JURISDICTION AND VENUE

4. The Court has jurisdiction over the subject matter of this action pursuant to 7 U.S.C. § 136n(c) and 28 U.S.C. §§ 1331 and 1345, and over Tzumi.

5. Venue is proper in the Southern District of New York pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1395(a) because Tzumi resides in, is located in, and conducts business in this judicial district.

THE PARTIES

6. Counterclaim Plaintiff is the United States on behalf of EPA.

7. Counterclaim Defendant Tzumi is a limited liability company organized under the laws of New York with its principal place of business at 16 East 34th Street, New York, New York 10016.

STATUTORY AND REGULATORY BACKGROUND

8. To ensure that pesticides will not generally cause unreasonable adverse risk to human health or the environment, Congress enacted FIFRA, to govern the production, sale, distribution, and use of pesticide products. 7 U.S.C. §§ 136 to 136y.

9. A “pesticide” is defined, as relevant here, to include “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest,” 7 U.S.C. § 136(u), and includes “antimicrobial pesticides,” which are pesticides that are intended to “disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms,” 7 U.S.C. § 136(mm). A “pest” includes, as relevant here, a “virus [or] bacteria . . . (except viruses, bacteria, or other micro-organisms on or in living man or other living animals).” 7 U.S.C. § 136(t).

10. A critical way in which FIFRA protects the public health is by making it illegal for any person to distribute or sell a pesticide that is not registered under FIFRA, unless an applicable exception to registration applies. 7 U.S.C. § 136j(a)(1)(A). The prohibition on distribution or sale of unregistered pesticides extends to “offers to sell” and advertisements for sale. 7 U.S.C. § 136(gg); 40 C.F.R. § 168.22(a).

11. EPA regulations further specify that registration is required where a distributor or seller “claims, states, or implies (by labeling or otherwise)” that a product “can or should be used as a pesticide,” 40 C.F.R. § 152.15(a)(1), or has “actual or constructive knowledge” that the product “will be used, or is intended to be used, for a pesticide purpose,” 40 C.F.R. § 152.15(c).

12. Registration is a critical step in ensuring the efficacy and safety of antimicrobial pesticides. When applying for pesticide registration, a registration applicant submits among other things, extensive product information (including, where necessary, test and other product efficacy data) to EPA. EPA reviews the application information and performs a rigorous, comprehensive scientific assessment of the product, including the product’s active and inert ingredients and the proposed uses of the product, to ensure that no unreasonable adverse effects on human health or the environment will occur when the product is used for its intended purpose and according to labeled directions. EPA particularly scrutinizes pesticides claimed to control human pathogens—commonly known as “public health claims” or “antimicrobial claims”—because of the potential adverse public health impacts if those products fail to work as claimed.

13. Registration also includes approval of a pesticide product’s label and other associated labeling. Approved labeling generally includes all permissible efficacy claims, instructions for the product’s use, and various warning and precautionary statements to protect the pesticide user, human health, and the environment.

14. FIFRA regulations at 40 C.F.R. § 152.25(f), provide an exemption for a class of pesticides known as “Minimum Risk Pesticides.” However, for a pesticide product to qualify for the exemption as a minimum risk pesticide, various conditions must be satisfied, including that the product not bear claims either to control or mitigate organisms that pose a threat to human health, 40 C.F.R. § 152.25(f)(3)(ii); the product’s ingredients are limited to those listed at 40 C.F.R. § 152.25(f)(1) and (f)(2); the product’s ingredients and specified information about the producer must be listed on the label, 40 C.F.R. § 152.25(f)(3)(i), 40 C.F.R. § 152.25(f)(3)(iii); and the label cannot include certain false or misleading statements found at 40 C.F.R. § 152.25(f)(3)(iv), 40 C.F.R. §§ 156.10(a)(5)(i)-(viii).

15. Section 16(c) of FIFRA provides federal district courts with jurisdiction to enforce, and to prevent and restrain violations of, the statute and its regulations. 7 U.S.C. § 136n(c).

16. Section 14(a) of FIFRA imposes liability for civil penalties for violations of the statute, to be assessed by EPA in an administrative proceeding in an amount up to \$20,805 per violation for violations occurring after November 2, 2015. 7 U.S.C. § 136l(a); 87 Fed. Reg. 1676 (Jan. 12, 2022). Section 13 authorizes other administrative remedies to be issued by EPA. The United States reserves the right to contend that violations found by the finder of fact in this judicial matter will, under the doctrine of collateral estoppel, control in a future administrative proceeding for civil penalties or other relief.

TZUMI’S VIOLATIONS OF FIFRA

17. In 2020, Tzumi introduced the Wipe Out! Products to retailers and consumers in what Tzumi admits was an “effort to respond to the public’s increased demand for disinfectant products during the COVID-19 public health crisis.”

18. The labeling of all three products made antimicrobial pesticidal claims suggesting that these products were intended to be used to disinfect surfaces, claims that make distribution and sale of the products illegal absent registration of the products under FIFRA (or an applicable exception). Moreover, these claims and Tzumi's actions as described below establish that Tzumi had actual and constructive knowledge that these products were pesticides as defined under FIFRA.

19. In distributing and selling unregistered antimicrobial pesticides during a global pandemic, Tzumi misled consumers and retailers and put the public at risk.

Wipe Out! Wipes

20. Beginning in at least August 2020, Tzumi sold and distributed millions of units of "Wipe Out! Wipes" to retailers for further sales to customers. The products bore Universal Product Code ("UPC") numbers 84135119599, 841351195997, and 841351195973. Tzumi has expressly stated that it intended these products to be sold to "lower income level customers."

21. The labels on these products implied to consumers that Wipe Out! Wipes could be used to disinfect surfaces of bacteria and viruses affecting public health. The labels proclaimed "Use it Anytime, Anywhere," and described the product as "Antibacterial Wipes" that "KILL[] GERMS FAST*" and "KILL[] 99.9% OF GERMS*" while specifying that the germs at issue were "*Escherichia Coli (E. coli), Staphylococcus Aureus (Staph)," and "Candida Albicans." The labels also emphasized that the product "Cleans and sanitizes." Although the back of the label also included language stating "[t]o decrease bacteria on the skin that could cause disease"—a non-pesticidal use under FIFRA, which defines "pest" to exclude "micro-organisms on or in living

man or other living animals,” 7 U.S.C. § 136(t)—the label as a whole conveys that the intended use is to “sanitize” “anywhere.”

22. This was not inadvertent, but instead reflects Tzumi’s intent to market the product as a surface disinfectant rather than a personal care product. When Tzumi publicly solicited designs for the Wipe Out! Wipes label, it described its intent to sell the product “in [the] cleaning section next to other disinfecting wipes” in retail stores. After selecting a winning design, Tzumi modified it to remove a prominent image of a hand and a reference to the product as a “hand sanitizer,” positioning the product instead to look like disinfectant wipes intended for use on surfaces. Further, Tzumi selected packaging for Wipe Out! Wipes that resembled the packaging used by registered surface disinfectant wipes such as Lysol: upright plastic canisters with similar text placement and a similar color scheme, rather than the horizontal wrapped bags that have been used for personal care wipes for decades.

23. Indeed, in early June 2020, Tzumi itself drafted and sent for posting on the website of Home Depot, its largest retailer, a “product description” of Wipe Out! Wipes for Home Depot’s website that expressly claimed that the product was a disinfectant for surfaces. The language stated, in part, that Wipe Out! Wipes “clean and disinfect with antibacterial power that kills 99.9% *of viruses and bacteria that can live on surfaces up to 48 hours*” and that “[t]hese all purpose wipes *remove common allergens, germs and messes on surfaces like kitchen counters, bathroom surfaces and more.*” (emphasis added). Home Depot in fact posted this description provided by Tzumi on its website until approximately September 2020. In September 2020, Home Depot removed from its website some of the references to disinfecting household surfaces pursuant to a request made by Tzumi on August 19, 2020 that Home Depot remove references to cleaning household surfaces and add the word “Hand Wipes.”

24. Consistent with Tzumi's misleading label, packaging, and marketing materials, retailers have regularly placed Wipe Out! Wipes with household surface cleaning and disinfection products, adjacent to and/or in close proximity to EPA-registered disinfectants in the cleaning supplies/products aisle, rather than with personal care or hand sanitizing products in the health and beauty aisle. For example, EPA and state agency inspectors have found Wipe Out! Wipes sold in cleaning supplies/products aisles in brick-and-mortar Home Depot, Safeway, Walgreens, and "At Home" stores. Similarly, EPA found Wipe Out! Wipes sold in the household cleaning supplies/disinfection section of retailers' websites, including homedepot.com, hannaford.com, and walmart.com.

25. Customer reviews on retailers' websites demonstrate that consumers themselves were misled into believing that these products should be used as a pesticide to disinfect surfaces. These reviews described the use of Wipe Out! Wipes to disinfect surfaces and compared Wipe Out! Wipes to registered pesticidal products sold by Clorox and Lysol. For example, reviews from October and November 2020 appearing either on Home Depot's website or Lowe's website stated:

- "I love these almost as much as my Lysol wipes. I use them on all of my hard surfaces and also for cleaning hands when we are not near a sink. I use them in the kitchen and bathrooms, doorknobs, countertops, toilets, sinks, tubs etc. They smell good, just as effective as Lysol and not as costly."
- "Good at sanitizing but not as good as Clorox wipes. These fall apart quickly. I use these to sanitize my door handles in my home. And my microwave. And even my refrigerator. I guess it's a personal decision on which sanitizing wipes you want to use."
- "I am a RN and I use these wipes all the time to clean not only my equipment but my countertops at home. Love!"
- "The[se] work great for disinfecting phones, doorknobs, and other stuff. . . . I do recommend."

- “I work with kids five days a week and I did not hesitate to take my Wipe Out antibacterial wipes to clean all touchable surfaces inside the classroom. They are perfect for cleaning dirtiness, fight[ing] germs, and/or bacteria, especially in these times of Covid-19. . . .”

26. No exception to FIFRA applies to this product. The product must be registered to be legally sold or distributed as a surface disinfectant. The product has not been registered.

27. Tzumi reports that starting in January 2021, after being contacted by EPA regarding its violations, it changed its label to include wording on the front describing the product as “hand wipes.” However, Wipe Out! Wipes bearing the original label remain on store shelves today.

28. Tzumi’s Wipe Out! Wipes have lost their pandemic-fueled popularity and are now found for sale at significantly lower price points, creating a risk that individuals with limited budgets will substitute this product for registered surface disinfectants thus raising environmental justice concerns.

Wipe Out! Multi-Surface Wipes

29. In October 2020, Tzumi also began selling a second product, “Wipe Out! Multi-Surface Wipes,” with labeling suggesting that it was intended for use to disinfect surfaces. The products bore UPC numbers 841351195591 and UPC 841351195577. The label displays the words “active ingredient” and “purpose: antibacterial” and has graphics of household appliances, bathroom fixtures, and surfaces.

30. The phrase “purpose: antibacterial” on this label is a pesticidal claim, requiring the product bearing this label to be registered with EPA in order to be lawfully distributed or sold. No

exception to the registration requirement applies to this product. The product has not been registered.

31. Through 2021, state agencies in Missouri and Indiana located Wipe Out! Multi-Surface Wipes bearing this label during marketplace inspections of Menards stores.

32. From at least October through November 2020, Tzumi distributed 472,281 units of Wipe Out! Multi-Surface Wipes bearing this label. Tzumi reports that it no longer offers the Wipe Out! Multi-Surface Wipes bearing this label for distribution to retailers, although some of the product so labeled remains on store shelves.

33. As with Wipe Out! Wipes, Wipe Out! Multi-Surface Wipes have lost their pandemic-fueled popularity and are now found for sale at significantly lower price points, creating a risk that individuals with limited budgets will substitute products bearing this label for registered surface disinfectants thus raising environmental justice concerns.

Wipe Out! Multi-Surface Decontaminant Spray

34. EPA has identified another unregistered Wipe Out! pesticide product, Wipe Out! Multi-Surface Decontaminant Spray (“Wipe Out! Decontaminant Spray”), sold bearing UPC numbers UPC 840139901364, 840139901379, and 840139901362. This product is a liquid formula that Tzumi has claimed is “exempt from pesticide registration” as a Minimum Risk Pesticide. Wipe Out! Decontaminant Spray, however, fails to comply with the conditions for an exemption as a minimum-risk pesticide set out at 40 C.F.R. § 152.25(f).

35. As an initial matter, the Wipe Out! Decontaminant Spray label displays the claims that the spray is “Antimicrobial;” “Decontaminant;” “Removes Mold and Mildew;” “Controls Algae Harmful Bacteria [sic].” These public health claims are prohibited for Minimum Risk Pesticides under 40 C.F.R. § 152.25(f)(3)(ii).

36. Moreover, the product label displays inert ingredients that are not listed at 40 C.F.R. § 152.25(f)(2)(i)-(iv). The Wipe Out! Decontaminant Spray label lists “[c]ommonly consumed food commodities,” a category of inert ingredient allowed by the regulation, but it fails to identify the specific food commodities in the product’s formula as required under 40 C.F.R. §§ 152.25(f)(2)(i) and 180.950(a). Moreover, Wipe Out! Decontaminant Spray also lists as inert ingredients chemical substances that are not specified in the regulation and that do not fall within the definition of food commodities, including “fragrance,” “colorant”, and “Polysorbate 20.” See 40 C.F.R. § 152.25(f)(2)(iv); *see also* <https://www.epa.gov/minimum-risk-pesticides/commonly-consumed-food-commodities> (color additives “are not to be considered to be a ‘commonly consumed food commodity’ under 40 C.F.R. § 180.950(a)”).

37. Further, by failing to provide Tzumi’s street address and telephone number, the label for Wipe Out! Decontaminant Spray does not provide the specified contact information required under 40 C.F.R. § 152.25(f)(3)(iii).

38. Finally, having failed to qualify as a Minimum Risk Pesticide, the product must not include any false or misleading statements or claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed.” 40 C.F.R. § 156.10(a)(5)(i)-(ix). However, Wipe Out! Decontaminant Spray makes unqualified and unreviewed safety claims, including, “Non-corrosive, Non-caustic” and “Non-Skin Irritant.”

39. An inspector from EPA discovered the Wipe Out! Decontaminant Spray during an inspection of an “At Home” store in Gaithersburg, Maryland in August 2021. The inspector observed the product on shelves adjacent to EPA-registered disinfectant products.

40. From February 2021 through April 2021, Tzumi sold 62,796 units of Wipe Out! Decontaminant Spray. Tzumi reports that it no longer distributes Wipe Out! Decontaminant Spray to retailers.

41. No exception to FIFRA applies to this product. The product must be registered to be legally sold or distributed. The product has not been registered.

CLAIM FOR RELIEF

Violations of FIFRA § 12(a)(1)(A): Distribution and Sale of Unregistered Pesticides (7 U.S.C. § 136j(a)(1)(A))

42. EPA restates the allegations of paragraphs 1 to 41, above.

43. Tzumi's Wipe Out! Wipes, Wipe Out! Multi-Surface Wipes, and Wipe Out! Decontaminant Spray are pesticides within the meaning of FIFRA.

44. Tzumi has not at any time registered Wipe Out! Wipes, Wipe Out! Multi-Surface Wipes, or Wipe Out! Decontaminant Spray with EPA.

45. It is unlawful under FIFRA for any person to offer for sale, sell, or distribute any pesticide if it is unregistered, absent exceptions not applicable here. 7 U.S.C. § 136j(a)(1)(A).

46. In violation of FIFRA, Tzumi offered for sale, sold, and distributed Wipe Out! Wipes, Wipe Out! Multi-Surface Wipes, and Wipe Out! Decontaminant Spray.

47. Tzumi's actions threaten irreparable harm to consumers who purchase these Wipe Out! Products under the misimpression that Tzumi's pesticidal products are comparable to EPA-registered products, even though EPA has not reviewed the Wipe Out! Products to determine the risks or benefits of using the products for their intended purpose and according to label directions.

These violations likewise threaten irreparable harm to EPA's interest in protecting the public and the environment from potential risks associated with unregistered pesticides.

48. Pursuant to 7 U.S.C. § 136n(c), the Court should issue an order (i) enjoining Tzumi from offering to sell, selling, or distributing unregistered pesticides, (ii) requiring Tzumi to mitigate the harms resulting from its violations of FIFRA, including by issuing appropriate public statements and statements to retailers regarding the status and proper use of these products, and (iii) providing other available equitable remedies.

PRAYER FOR RELIEF

WHEREFORE, EPA respectfully requests that this Court:

- i. Enter judgment against Tzumi and in favor of EPA for the violations alleged in this counterclaim;
- ii. Enter an order enjoining Tzumi from distributing or selling unregistered pesticides;
- iii. Order that Tzumi mitigate the harms resulting from its conduct; and
- iv. Grant such other and further equitable and other relief as the Court deems just and appropriate.

Dated: New York, New York
June 13, 2022

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York

By: /s/ Allison M. Rovner
ALLISON M. ROVNER
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: (212) 637-2691
Fax: (212) 637-2750
E-mail: allison.rovner@usdoj.gov

Of Counsel:

Jeannie Yu, Assistant Regional Counsel

U.S. Environmental Protection Agency, Region 2