John A. Conkle (SB# 117849)
John.Conkle@ThompsonHine.com
Chelsea A. Bernard (SB# 343509)
Chelsea.Bernard@ThompsonHine.com
THOMPSON HINE LLP
3130 Wilshire Boulevard, Suite 500
Santa Monica, California 90403-2351
Phone: (310) 998-9100 • Fax: (310) 998-9109

Eric N. Heyer (*pro hac vice* motion forthcoming)
Eric.Heyer@ThompsonHine.com
James C. Fraser (*pro hac vice* motion forthcoming)
James.Fraser@ThompsonHine.com
THOMPSON HINE LLP
1919 M Street, N.W., Suite 700
Washington, DC 20036-3537
Phone: (202) 331-8800 • Fax: (202) 331-8330

Attorneys for Plaintiff Huff and Puffers, LLC d/b/a Huff and Puffers

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, SOUTHERN DIVISION

Huff and Puffers, LLC d/b/a Huff and Puffers,

Plaintiff,

v.

U.S. Food and Drug Administration; Robert M. Califf, M.D., Commissioner of Food and Drugs; U.S. Department of Health and Human Services; Xavier Becerra, J.D., Secretary of Health and Human Services,

Defendants.

Case No. 8:24-cv-2110

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

ACTION SEEKING STATEWIDE OR NATIONWIDE RELIEF

Plaintiff Huff and Puffers, LLC brings this Complaint for declaratory and injunctive relief against Defendants the United States Food and Drug Administration ("FDA"), Robert M. Califf, M.D. (in his official capacity as the Commissioner of Food and Drugs), the United States Department of Health and Human Services ("HHS"), and Xavier Becerra, J.D. (in his official capacity as the Secretary of Health and Human Services). In support thereof, Plaintiff states as follows:

INTRODUCTION

1. Plaintiff brings this Complaint to enjoin Defendants' unconstitutional administrative proceeding to levy a civil money penalty of $20,678 against Plaintiff. Under the Supreme Court's ruling in *SEC v. Jarkesy*, 144 S. Ct. 2117 (2024), Defendants' administrative proceeding violates Plaintiff's right to a jury trial under the Seventh Amendment to the United States Constitution.

2. The remedy for this constitutional violation is an order declaring that Defendants' administrative proceedings are unconstitutional and enjoining such administrative proceedings.

PARTIES

3. Plaintiff Huff and Puffers, LLC is a California limited liability company with its principal place of business at 12105 Brookhurst Street, Suite D/E, Garden Grove, CA 92840.

4. Defendant United States Food and Drug Administration is an executive branch agency of the federal government and is headquartered at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

5. Defendant Robert M. Califf, M.D. (sued here only in his official capacity), is the Commissioner of Food and Drugs and an officer of the United States. His office is at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

6. Defendant United States Department of Health and Human Services ("HHS") is an executive branch agency of the federal government and is headquartered at 200 Independence Avenue, S.W., Washington, DC 20201.

7. Defendant Xavier Becerra, J.D., (sued here only in his official capacity) is the Secretary of Health and Human Services and an officer of the United States. His office is at 200 Independence Avenue, S.W., Washington, DC 20201.

8. FDA is an operating division of HHS. The Commissioner of Food and Drugs reports to the Secretary of Health and Human Services.

JURISDICTION AND VENUE

9. This action arises under the Constitution and laws of the United States. Therefore, the Court has subject matter jurisdiction under 21 U.S.C. §§ 1331, 1346.

10. Under the Supreme Court's decision in *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023), the Federal Food, Drug, and Cosmetic Act's ("FDCA") statutory review provision for civil money penalties does not displace the Court's federal question jurisdiction over a constitutional challenge to the FDCA provision that allows civil money penalties to be assessed in an administrative proceeding.

11. The Declaratory Judgment Act authorizes the Court to grant Plaintiff's request for declaratory relief. 28 U.S.C. §§ 2201-2202.

12. Venue is proper in this district under 28 U.S.C. § 1391(c)(2) and (e)(1)(C).

RELEVANT LAW AND FACTS

A. The Seventh Amendment and *SEC v. Jarkesy*

13. The Seventh Amendment to the United States Constitution guarantees a right to a jury in suits "at common law" where the amount at issue exceeds twenty dollars. *See* U.S. Const. amend VII.

14. In *Jarkesy*, 144 S. Ct. 2117, the Supreme Court held that the Seventh Amendment right to a jury trial applies to the Securities Exchange Act's civil penalties for securities fraud. The Court reasoned that the civil penalties at issue in that case "are designed to punish and deter, not compensate," and "are therefore 'a type of remedy at common law that could only be enforced in courts of law.'" *Id.* at 2130 (*quoting Tull v. United States*, 481 U.S. 412, 422 (1987)).

15. In reaching its decision in *Jarkesy*, the Court provided the following analysis:

16. "[T]he Framers used the term 'common law' in the [Seventh] Amendment 'in contradistinction to equity, and admiralty, and maritime jurisprudence.'" *Jarkesy*, 144 S. Ct. at 2128 (*quoting Parsons v. Bedford*, 28 U.S. 433, 446 (1830)). In other words, the Seventh Amendment "embrace[s] all suits which are not of equity or admiralty jurisdiction." *Jarkesy*, 144 S. Ct. at 2128 (*quoting Parsons*, 28 U.S. at 447).

17. "The Seventh Amendment extends to a particular statutory claim if the claim is 'legal in nature.'" *Jarkesy*, 144 S. Ct. at 2128 (*quoting Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 53 (1989)).

18. "To determine whether a suit is legal in nature," courts must "consider the cause of action and the remedy it provides." *Jarkesy*, 144 S. Ct. at 2129. "[T]he remedy" is "the more important consideration." *Id.* (internal quotation marks and citation omitted.)

19. "While monetary relief can be legal or equitable, money damages are the prototypical common law remedy." *Id.*

20. "What determines whether a monetary remedy is legal is if it is designed to punish or deter the wrongdoer, or, on the other hand, solely to 'restore the status quo.'" *Id.* (*quoting Tull*, 481 U.S. at 422).

21. "[A] civil sanction that cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes, is punishment." *Jarkesy*, 144 S. Ct. at 2129 (*quoting Austin v. United States*, 509 U.S. 602, 610 (1993)).

22. "[W]hile courts of equity could order a defendant to return unjustly obtained funds, only courts of law issued monetary penalties to 'punish culpable individuals.'" *Jarkesy*, 144 S. Ct. at 2129 (*quoting Tull*, 481 U.S. at 422).

23. "Applying these principles," the Supreme Court has "recognized that 'civil penalti[es are] a type of remedy at common law that could only be enforced in courts of law.'" *Jarkesy*, 144 S. Ct. at 2129 (*quoting Tull*, 481 U.S. at 422).

24. The Securities Exchange Act conditions the availability of civil penalties on a variety of factors, several of which "concern culpability, deterrence, and recidivism." *Jarkesy*, 144 S. Ct. at 2129. "Because [such factors] tie the availability of civil penalties to the perceived need to punish the defendant rather than to restore the victim, such considerations are legal rather than equitable." *Id.*

25. "The same is true of the [Securities Exchange Act's] criteria that determine the size of the available remedy." *Jarkesy*, 144 S. Ct. at 2129. The statute establishes three "tiers" of penalties, with "[e]ach successive tier authoriz[ing] a larger monetary sanction" conditioned "on the culpability of the defendant and the need for deterrence, not the size of the harm that must be remedied." *Id.* at 2129-30. "Indeed, showing that a victim suffered harm is not even required to advance a defendant from one tier to the next. Since nothing in this analysis turns on restoring the status quo, these factors show that these civil penalties are designed to be punitive." *Id.* at 2130 (internal quotation marks, brackets and citation omitted).

26. "The final proof that this remedy is punitive is that the SEC is not obligated to return the money to victims." *Id.* at 2130. "Such a penalty by definition does not 'restore the status quo' and can make no pretense of being equitable." *Id.* at 2130 (*quoting Tull*, 481 U.S. at 422).

B. *Axon Enterprise, Inc. v. FTC*

27. In *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023), the Supreme Court held that district courts have jurisdiction to hear constitutional challenges to the Federal Trade Commission's and the SEC's processes for adjudicating enforcement actions through administrative law judges ("ALJs").

28. Both the FTC and the SEC argued that district courts do not have jurisdiction to address constitutional challenges to the administrative enforcement

proceedings because the relevant statutes provide that the administrative findings can be challenged in a circuit court. The Supreme Court rejected that argument based on three factors:

29. First, the Court found that precluding a district court challenge to the administrative enforcement proceeding would "foreclose all meaningful judicial review" of the plaintiffs' claim. *Axon*, 598 U.S. at 186 (*quoting Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212 (1994)). The Court reasoned that waiting for the circuit court to rule on the constitutional challenge would not provide meaningful judicial review because by that point the plaintiffs would already have suffered their claimed injury—being subjected to an "unconstitutional" proceeding. *Axon*, 598 U.S. at 191.

30. Second, the Court found that the plaintiffs' claims were "wholly collateral to [the FTC and SEC statutory] review provisions." *Axon*, 598 U.S. at 186 (*quoting Thunder Basin*, 510 U.S. at 212). The Court reasoned that plaintiffs' claims were a challenge to the agencies' constitutional authority to conduct the administrative enforcement actions, not a challenge to the decisions made by the agencies during those administrative proceedings. *Axon*, 598 U.S. at 192-193.

31. Finally, the Court found that the plaintiffs' claims were "outside the [agencies'] expertise." *Axon*, 598 U.S. at 186 (*quoting Thunder Basin*, 510 U.S. at 212). For example, the Court noted that while agencies like the FTC "know[] a good deal about competition policy," they know "nothing special about" issues of constitutional law. *Axon*, 598 U.S. at 194. "For that reason," the Court had previously observed that "'agency adjudications are generally ill suited to address structural constitutional challenges.'" *Id.* at 194-95 (*quoting Carr v. Saul*, 593 U.S. 83, 92 (2021).

C. FDCA Civil Money Penalties

32. Section 301(a) of the Food, Drug and Cosmetic Act ("FDCA") prohibits the interstate distribution of various of types of "adulterated" and "misbranded"

products. *See* 21 U.S.C. § 331(a) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded").

33. Persons who violate section 301(a) are subject to criminal prosecution in a district court. *See* 21 U.S.C. § 333(a)(1) ("Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1000, or both.").

34. The FDCA also authorizes FDA to assess civil money penalties well above $1,000 against persons for certain violations of section 301(a). *See* 21 U.S.C. § 333(f), (g).

35. However, FDCA civil money penalty cases are not adjudicated in a district court. Instead, they are adjudicated by an administrative law judge ("ALJ") in the Civil Remedies Division of the HHS Departmental Appeals Board ("DAB"). *See* 21 U.S.C. § 333(f)(5)(A); 21 C.F.R. Part 17.

36. As relevant here, the FDCA authorizes an ALJ to assess a civil money penalty of $15,000 for each violation of section 301(a) with respect to tobacco products, up to $1,000,000 for all such violations adjudicated in a single proceeding. 21 U.S.C. § 333(f)(9)(A).

37. Similarly to the Securities Exchange Act, the FDCA directs the ALJ to consider factors concerning culpability, deterrence, and recidivism when determining the appropriate amount of a civil money penalty. *See* 21 U.S.C. § 333(f)(5)(B) (listing factors that include the "gravity of the violation," the respondent's "history" of "prior … violations," and the respondent's "degree of culpability").

38. Indeed, the FDCA also authorizes "enhanced" civil money penalties for certain "intentional" violations with respect to tobacco products. *See* 21 U.S.C. § 333(f)(9)(B)(i) (authorizing a penalty of $250,000 per violation and additional six-to-

seven-figure penalties for violations that continue after FDA provides notice of the violation).[1]

39. An ALJ does not have the authority to find that FDA's civil money penalty proceedings are unconstitutional. *See* 21 C.F.R. § 17.19(c) (stating the ALJ "does not have the authority to find Federal statutes or regulations invalid").

40. The ALJ's decision in a civil money penalty proceeding may be appealed to a panel of three ALJs at the DAB's Appellate Division. 21 C.F.R. § 17.47.

41. ALJs in the DAB's Appellate Division do not have the authority to find that the FDA's civil money penalty proceedings are unconstitutional. 21 C.F.R. § 17.47(g).

42. Any person who is assessed a civil money penalty and loses his appeal at the Appellate Division may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit or in any other circuit in which such person resides or transacts business. 21 U.S.C. § 333(f)(6).

43. All money collected from FDA's civil money penalty proceedings are "deposited as miscellaneous receipts in the Treasury of the United States." 21 C.F.R. § 17.54.

D. FDA's Administrative Complaint Against Plaintiff

44. On June 3, 2024, the FDA's Center for Tobacco Products ("CTP") filed an administrative complaint for a civil money penalty of $20,678 against Plaintiff Huff and Puffers, LLC ("Plaintiff" or "H&P") in the Civil Remedies Division of the HHS Departmental Appeals Board. (*See* Exhibit A, Administrative Complaint at ¶ 1)

45. CTP's Administrative Complaint alleges that H&P sold an "adulterated" and "misbranded" tobacco product (an electronic cigarette that has not been

[1] The FDCA's civil money penalty amounts are adjusted for inflation annually. *See* 45 C.F.R. § 102.3.

authorized for sale by FDA) to an adult (21 years old or older) undercover FDA agent. (*Id.* at ¶ 20)

46. On July 5, 2024, H&P filed its Answer to the Administrative Complaint. (*See* Exhibit B, Answer to Administrative Complaint)

47. In its Answer, H&P stated that it does not waive its Seventh Amendment right to a jury trial and therefore the Seventh Amendment prohibits the Departmental Appeals Board from adjudicating its case. (*Id.* at 3)

48. H&P also asserted the defenses of unclean hands and selective enforcement because CTP has not sought civil money penalties from "Big Tobacco" companies (*e.g.*, R.J. Reynolds, Altria) for selling "adulterated" tobacco products (electronic cigarettes that have not been authorized for sale by FDA) even though it is undisputed that those companies sell and/or have sold such "adulterated" products. (*Id.*)

49. Finally, H&P asserted that a civil money penalty of $20,678 is excessive under the factors specified in 21 U.S.C. § 331(f)(5)(B). Electronic cigarettes are generally considered to be much less harmful than combustible (traditional) cigarettes. Therefore, the sale of an unauthorized electronic cigarette to an adult is a much less serious violation of the FDCA than the sale of a combustible cigarette to a minor. However, CTP generally seeks a civil money penalty of only $345 for the sale of a combustible cigarette to a minor.

50. As of the date of the filing of this Complaint in this Court, the ALJ assigned to the proceeding against H&P in the Civil Remedies Division of the Departmental Appeals Board has not scheduled a hearing to adjudicate CTP's Administrative Complaint.

COUNT I

Declaratory and Injunctive Relief on the Ground that FDA's Civil Money Penalty Proceeding Violates the Seventh Amendment To The United States Constitution

51. Pursuant to Federal Rule of Civil Procedure 10(c), Plaintiff H&P adopts by reference all preceding paragraphs as if fully set forth herein.

52. The Seventh Amendment's right to a jury trial extends to statutory claims that are "legal in nature." *Jarkesy*, 144 S. Ct. at 2128.

53. A statutory claim is "legal in nature" when it provides a monetary remedy that "is designed to punish or deter the wrongdoer." *Id.* at 2129.

54. A monetary remedy "is designed to punish or deter the wrongdoer" when the amount of the monetary remedy is based on factors which "concern culpability, deterrence, and recidivism," and/or the money collected as a remedy is kept by the government rather than returned to the alleged "victim[s]." *Id.* at 2129.

55. The Seventh Amendment's right to a jury trial extends to civil money penalties under the FDCA because those penalties are designed to punish or deter the wrongdoer.

56. FDCA civil money penalties are designed to punish or deter the wrongdoer because the amount of the penalties is based on factors which concern culpability, deterrence, and recidivism.

57. FDCA civil money penalties are designed to punish or deter the wrongdoer because the penalties collected by the government are deposited as miscellaneous receipts in the Treasury of the United States.

58. FDA's civil money penalty proceeding against H&P violates H&P's Seventh Amendment to a jury trial.[2]

[2] The dissent in *Jarkesy* argued that the SEC's civil money penalties fell within the "public rights" exception to the Seventh Amendment as construed in *Atlas Roofing*

59. FDA's civil money penalty proceeding subjects H&P to irreparable harm by forcing H&P to incur the time and expense of an unconstitutional proceeding.

60. The FDCA's statutory review provision for civil money penalties does not deprive this Court of jurisdiction to adjudicate H&P's constitutional challenge to the administrative civil money penalty proceeding because:

a. Requiring H&P to wait until a circuit court reviews any judgment entered by the HHS Departmental Appeals Board would not provide H&P with meaningful judicial review because H&P will already have suffered its claimed injury—the time and expense of an unconstitutional proceeding—by the time the circuit court reviews the judgment;

b. H&P's claim is collateral to the FDCA statutory review provision because the claim is a constitutional challenge to the administrative proceeding itself, not a challenge to a decision made during that proceeding; and

c. H&P's claim is outside of HHS's and FDA's expertise. HHS and FDA are public health agencies; they are not agencies with expertise in constitutional law.

Co. v. Occupational Safety and Health Review Commission, 430 U.S. 442 (1977). In *Atlas Roofing*, the Court held that the Seventh Amendment did not prevent a federal agency—OSHA—from adjudicating alleged violations of the agency's workplace safety regulations because such claims were not tried in courts of law prior to the adoption of the Seventh Amendment (1791). *See Atlas*, 430 U.S. at 450. But the majority in *Jarkesy* held that the "public rights" exception did not apply to the SEC's civil penalties for securities fraud because claims for fraud were being tried in courts of law by the time the Seventh Amendment was adopted. *Jarkesy*, 144 S. Ct. at 2137. Similarly, claims for the sale of "adulterated" products were being tried in courts of law by the time the Seventh Amendment was adopted. *See, e.g.*, H.W. Schultz, *Food Law Handbook* 2-3 (1981) (noting that in 1785 Massachusetts adopted a statute authorizing the Commonwealth's Supreme Judicial Court to convict persons for selling any "diseased, corrupted, contagious or unwholesome provisions" and to sentence such persons to "be punished by fine, imprisonment, [and] standing in the pillory"). Therefore, *Atlas Roofing* does not apply to FDCA civil money penalties.

REQUEST FOR RELIEF

61. Plaintiff respectfully requests that this Court enter judgment in its favor that includes the following relief:

a. A declaration pursuant to 28 U.S.C. § 2201 that the FDCA's civil money penalty provisions for tobacco products, 21 U.S.C. § 331(f)(9) violate the Seventh Amendment to the Constitution;

b. A declaration pursuant to 28 U.S.C. § 2201 that the FDA's civil money penalty proceeding against Plaintiff violates the Seventh Amendment to the Constitution.

c. An order requiring FDA's Center for Tobacco Products to dismiss with prejudice its Administrative Complaint against Plaintiff;

d. An order prohibiting HHS and FDA from adjudicating civil money penalties in administrative proceedings;

e. An order prohibiting HHS and FDA from adjudicating civil money penalties against Plaintiff in an administrative proceeding.

f. An order awarding Plaintiff its costs, expenses, and fees (including attorney fees) pursuant to 28 U.S.C. § 2412; and

g. An order granting such further relief as is necessary and appropriate.

Dated: September 27, 2024

John A. Conkle
Chelsea A. Bernard
THOMPSON HINE LLP

By: */s/ John A. Conkle*
John A. Conkle
Eric N. Heyer
(*pro hac vice* motion forthcoming)
James C. Fraser
(*pro hac vice* motion forthcoming)

Attorneys for Plaintiff Huff and Puffers, LLC d/b/a Huff and Puffers

EXHIBIT A

UNITED STATES OF AMERICA
BEFORE THE DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of: Center for Tobacco Products, Complainant, v. Huff and Puffers, LLC d/b/a Huff and Puffers, Respondent.	**ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY** FDA Docket No. FDA-2024-H-2562 CRD Docket No. T-24-3102

INTRODUCTION

1. The Center for Tobacco Products (CTP), Food and Drug Administration (FDA), United States Department of Health and Human Services, seeks a civil money penalty (CMP) in the amount of $20,678 from Huff and Puffers, LLC d/b/a Huff and Puffers (Respondent), for introducing into interstate commerce an electronic nicotine delivery system (ENDS) product that lacks the premarketing authorization required under the Federal Food, Drug, and Cosmetic Act (Act).

LEGAL AUTHORITY

2. FDA has the authority to seek a civil money penalty from any person who violates a requirement of the Act related to tobacco products. 21 U.S.C. § 333(f)(9).

3. A “tobacco product” means “any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption,

including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr).

4. It is a violation of the Act to introduce or deliver for introduction into interstate commerce or cause the introduction or delivery for introduction into interstate commerce, any tobacco product that is adulterated or misbranded. 21 U.S.C. § 331(a).

5. "Interstate commerce" includes "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b).

6. As of August 8, 2016, pursuant to 21 U.S.C. §§ 387a and 387f(d) (Section 906(d) of the Act), FDA deemed additional products meeting the definition of a tobacco product, except accessories to these newly deemed products, to be subject to regulation under the Act. These products include, but are not limited to, electronic nicotine delivery systems (including e-cigarettes), e-liquids, and pipe tobacco. *See* Final Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016), available at https://federalregister.gov/a/2016-10685.

7. The Act defines "new tobacco product" at 21 U.S.C. § 387j(a)(1) to include "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007."

8. All new tobacco products must have FDA authorization prior to their marketing. *See* 21 U.S.C. § 387j(a)(2)(A).

9. A new tobacco product is exempt from this premarket authorization requirement only if there is a substantial equivalence (SE) or substantial equivalence exemption order ("found-exempt order") in effect for such product. 21 U.S.C. §§ 387j(a)(2)(A) and 387e(j)(3)(A).

10. A new tobacco product that is required by 21 U.S.C. § 387j(a) to have premarket review and does not have a Marketing Granted Order (MGO) permitting marketing of the new tobacco product in effect under 21 U.S.C. § 387j(c)(1)(A)(i), is adulterated under 21 U.S.C. § 387b(6)(A).

11. Under 21 U.S.C. § 387c(a)(6), a new tobacco product is misbranded if a "notice or other information respecting it was not provided as required" under the SE or SE exemption pathway, including an SE report or an abbreviated report.

12. Retailers who violate a requirement of the Act which relates to tobacco products shall be liable for a civil money penalty up to $20,678 for each such violation, not to exceed $1,378,541 for all violations adjudicated in a single proceeding. 21 U.S.C. § 333(f)(9)(A); 21 C.F.R. § 17.2.

CURRENT ALLEGATIONS

13. Respondent sells and/or distributes tobacco products through its online establishment that does business under the name Huff and Puffers, which is accessible at the URL: https://www.huffandpuffers.com.

14. On May 31, 2023, although there is no statutory requirement for FDA to do so, CTP issued a Warning Letter to Respondent, stating that, among other things,

the new tobacco products that Respondent sells and/or distributes are adulterated and misbranded because they lack the required FDA marketing authorization order.

15. On December 13, 2023, an FDA-commissioned inspector conducted an inspection of Huff and Puffers at the URL: https://www.huffandpuffers.com. During this inspection, FDA purchased Respondent's EB Design BC5000 Disposable Vape 4% Nicotine Sakura Grape ENDS product.

16. Respondent shipped the EB Create BC5000 Sakura Grape ENDS product, a different ENDS product / e-liquid product than the one ordered, from California to FDA in Virginia.

17. Respondent's EB Create BC5000 Sakura Grape ENDS product (hereinafter Respondent's ENDS product(s))/e-liquid product(s) is a "new tobacco product" because it was not commercially marketed in the United States as of February 15, 2007.

18. Respondent's ENDS product does not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i) and it is, therefore, adulterated under 21 U.S.C. § 387b(6)(A).

19. Neither an SE report nor an abbreviated report has been submitted for Respondent's ENDS product, and it is, therefore, misbranded under 21 U.S.C. § 387c(a)(6).

20. Respondent introduced or delivered for introduction into interstate commerce or caused the introduction or delivery for introduction into interstate commerce of, this adulterated and misbranded product, in violation of 21 U.S.C. § 331(a).

RESPONDING TO COMPLAINT

21. Respondent must respond to this Complaint. The cover letter provides information on options for responding. Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. 21 C.F.R. § 17.9. The Answer will be deemed to be a request for a hearing unless the Answer states otherwise. Failure to file an Answer within 30 days after service of the Complaint may result in a default order imposing the proposed civil money penalty. 21 C.F.R. § 17.11. The Answer must be filed with the Departmental Appeals Board, Civil Remedies Division. Answers should be filed electronically at https://dab.efile.hhs.gov or, to request a waiver from filing an Answer electronically with DAB E-File, Respondent should call the Civil Remedies Division of the Departmental Appeals Board at 844-880-5720. For additional instructions on how to file an Answer, *see* the Cover Letter that accompanies this Complaint.

22. Respondent has the right, but is not required to, retain counsel for representation.

REQUEST FOR RELIEF

23. CTP respectfully requests an order assessing a civil money penalty against Respondent in the amount of $20,678.

DATED: June 3, 2024

Respectfully submitted,

/s/

Elizabeth Teter-Gossmann
Attorney for Complainant
Center for Tobacco Products
United States Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (301) 332-9869
Email: elizabeth.teter@fda.hhs.gov

EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION

Center for Tobacco Products, Complainant, v. Huff and Puffers, LLC, d/b/a Huff and Puffers Respondent.	:	FDA Docket No. FDA-2024-H-2562 CRD Docket No. T-24-3102

ANSWER TO COMPLAINT

In accordance with 21 C.F.R. § 17.9, Respondent Huff and Puffers, LLC, requests a hearing and submits the following answer to the complaint in this case.

Response to Allegations in the Complaint (21 C.F.R. § 17.9(b)(1))

Because the allegations in paragraph 1 of the complaint set forth only an introduction to the complaint, no response to those allegations is required. To the extent a response is required, Respondent denies those allegations.

Because the allegations in paragraphs 2-12 of the complaint set forth only legal conclusions, no response to those allegations is required. To the extent a response is required, Respondent denies those allegations.

Respondent admits the allegations in paragraph 13 of the complaint.

Respondent admits the allegation in paragraph 14 of the complaint that on May 31, 2023, CTP sent Respondent a Warning Letter alleging that Respondent sold a new tobacco product that

did not have a marketing granted order. To the extent any further response to the allegations in paragraph 13 of the complaint is required, Respondent denies those allegations.

Respondent lacks sufficient information upon which to admit or deny the allegations in paragraphs 15-16 of the complaint. Respondent therefore denies those allegations.

Respondent admits the allegation in paragraph 17 that EB Create BC5000 Sakura Grape is a "new tobacco product" because it was not commercially marketed in the United States as of February 15, 2007. To the extent any further response to the allegations in paragraph 17 of the complaint is required, Respondent denies those allegations.

Respondent admits the allegation in paragraph 18 of the complaint that EB Create BC5000 Sakura Grape does not have an MGO in effect under 21 U.S.C. § 387c(a)(6). To the extent any further response to the allegations in paragraph 18 of the complaint is required, Respondent denies those allegations.

Respondent admits the allegation in paragraph 19 of the complaint that neither an SE report nor an abbreviated report has been submitted for EB Create BC5000 Sakura Grape. To the extent any further response to the allegations in paragraph 19 of the complaint is required, Respondent denies those allegations.

Assuming the allegations in paragraph 20 of the complaint refer to the shipment alleged in paragraph 16 of the complaint, Respondent lacks sufficient information upon which to admit or deny the allegations in paragraph 20 of the complaint. Respondent therefore denies the allegations in paragraph 20 of the complaint.

To the extent Respondent has not adequately responded to any allegations in the complaint, respondent denies those allegations.

Defenses (21 C.F.R. § 17.9(b)(2))

Under the Seventh Amendment to the United States Constitution, Respondent has a right to a jury trial on CTP's request for a civil money penalty. *See SEC v. Jarkesy*, 2024 U.S. LEXIS 2847 (Jun. 27, 2024). Respondent does not waive its right to a jury trial on CTP's request for a civil money penalty. Therefore, the Seventh Amendment prohibits the Departmental Appeals Board from adjudicating this case.

Upon information and belief, CTP has not sought civil money penalties from "Big Tobacco" companies (e.g., R.J. Reynolds, Altria) that market ENDS products without an MGO. Therefore, CTP's request for a civil money penalty in this case is barred by the doctrines of unclean hands and selective enforcement. *See, e.g., United States v. Innovative BioDefense, Inc.*, 2019 U.S. Dist. LEXIS 221930, *10-11 (C.D. Cal. Aug. 22, 2019).

Reasons for Reduced Penalty (21 C.F.R. § 17.9(b)(3))

The requested civil money penalty is excessive in light of the factors specified in 21 U.S.C. § 331(f)(5)(B). Specifically, CTP does not allege that Respondent sold a tobacco product to a purchaser under the age of 21. Moreover, CTP alleges that Respondent sold a product that is generally considered to be less harmful than combustible cigarettes. Finally, Respondent notes that CTP requests much lower civil money penalties in cases where a retailer is alleged to have sold combustible cigarettes to an underage purchaser, which is a much more serious violation than selling an ENDS product to an adult.

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s/ James C. Fraser
James C. Fraser (D.C. Bar No. 460303)
Thompson Hine LLP
1919 M Street, N.W., Suite 700
Washington, DC 20036-3537
james.fraser@thompsonhine.com
(202) 973-2730 (phone)
(202) 331-8330 (fax)

Counsel for Respondent, Huff and Puffers, LLC, d/b/a Huff and Puffers