

1 Joel Sannes, Ariz. Bar No. 015999
jsannes@lakeandcobb.com
2 **LAKE & COBB, P.L.C.**
1095 W Rio Salado Parkway, Suite 206
3 Tempe, Arizona 85281
Telephone: 602-523-3000
4 Telefax: 602-523-3001
Local Counsel for Plaintiff

5
6 Mr. Jonathan M. Weis (pro hac vice application forthcoming)
jweis@lgattorneys.com
7 Mr. Mitchell S. Chaban (pro hac vice application forthcoming)
mchaban@lgattorneys.com

8 **LEVIN GINSBURG**
180 North LaSalle Street, Suite 3200
Chicago, Illinois 60601-2800
9 Telephone: 312-368-0100
Telefax: 312-368-0111
10 *Lead Counsel for Plaintiff*

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12 **IN THE UNITED STATES DISTRICT COURT**
13 **FOR THE DISTRICT OF ARIZONA**

14 **BBK TOBACCO & FOODS, LLP, an Arizona**
15 **limited liability partnership,**

16 **Plaintiff,**

17 **v.**

18 **U.S. FOOD AND DRUG ADMINISTRATION;**
MARGARET A. HAMBURG, Commissioner of
19 **the United States Food and Drug**
Administration; U.S. DEPARTMENT OF
20 **HEALTH AND HUMAN SERVICES; and**
KATHLEEN SEBELIUS, Secretary of the
21 **United States Department of Health and**
Human Services,

22 **Defendants.**

Case No. 09-2111

COMPLAINT

1 9. The Act amends the Federal Food, Drug and Cosmetic Act to define
2 “tobacco product” as “any product *made or derived from tobacco* that is intended for
3 human consumption, including any component, part, or accessory of a tobacco
4 product (except for raw materials other than tobacco used in manufacturing a
5 component, part, or accessory of a tobacco product).” Pub L. No. 111-31 § 101, 21
6 U.S.C. § 321(rr)(1) (emphasis added). Flavored Paper *sold separately* is not a
7 component of, a part of, or an accessory of, a tobacco product and is not made or
8 derived from tobacco and is thus, not a tobacco product.

9 10. Pursuant to the Act, the FDA’s authority is initially limited to “cigarettes,
10 cigarette tobacco, roll-your-own tobacco, and smokeless tobacco” and does not
11 extend to Flavored Paper. See Pub. L. 111-31 §901(b), 21 U.S.C. § 387a(b). The FDA
12 has also not promulgated any regulations pursuant to the Act and is therefore limited
13 to regulate only the tobacco products specifically listed in Section 901(b). Flavored
14 Paper is not a cigarette, cigarette tobacco, roll-your-own tobacco, or smokeless
15 tobacco. Therefore the FDA has no authority to regulate Flavored Paper.

16 11. The Act includes a special rule regarding the flavoring of cigarettes:

17 SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date
18 of enactment of the Family Smoking Prevention and Tobacco Control Act,
19 a cigarette or any of its component parts (including the tobacco, filter, or
20 paper) shall not contain, as a constituent (including a smoke constituent)
or additive, an artificial or natural flavor (other than tobacco or menthol) or
an herb or spice, including strawberry, grape, orange, clove, cinnamon,
pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee,
that is a characterizing flavor of the tobacco product or tobacco smoke.

21 Pub. L. 111-31 §907(a)(1)(A), 21 U.S.C. §387g(a)(1)(A).
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1 12. The legislative history of the Act indicates that Congress intended the
2 prohibition of “characterizing flavors” to apply to cigarettes, and makes no mention of
3 Flavored Paper sold separately. See H.R. No. 11-58, 2009 U.S.C.C.A.N. 468
4 (stating that the FDA’s authority under the Act would include “[s]etting national
5 standards for tobacco products, including a ban on *cigarettes* that contain certain
6 additive or flavors (other than tobacco or menthol) that are a characterizing flavor of
7 the tobacco product or tobacco smoke” and that “section 907(a)(1) is intended to
8 prohibit the manufacture and sale of *cigarettes* with certain “characterizing flavors” that
9 appeal to youth”) (emphasis added).

10 13. The Act provides that “cigarette”

11 (A) means a product that—

12 (i) is a tobacco product; and

13 (ii) meets the definition of the term ‘cigarette’ in section 3(1) of the
14 Federal Cigarette Labeling and Advertising Act; and

15 (B) includes tobacco, in any form, that is functional in the product, which,
16 because of its appearance, the type of tobacco used in the filler, or its
17 packaging and labeling, is likely to be offered to, or purchased by,
18 consumers as a cigarette or as roll-your-own tobacco.

19 Pub. L. 111-31 § 900(3), 21 U.S.C. § 387(3). The Federal Cigarette Labeling and
20 Advertising Act (“FCLAA”) defines “cigarette” as

21 (A) any roll of tobacco wrapped in paper or in any substance not containing
22 tobacco, and

23 (B) any roll of tobacco wrapped in any substance containing tobacco which,
24 because of its appearance, the type of tobacco used in the filler, or its
25 packaging and labeling, is likely to be offered to, or purchased by,
26 consumers as a cigarette described in subparagraph (A).

27 15 U.S.C. 1332(1). The Act and the FCLAA’s definitions of cigarette clearly include
28 only products that include tobacco. Flavored Paper sold separately does not include
29 tobacco and are, therefore, not cigarettes under the FCLAA or the Act.

1 14. Flavored Paper also does not meet the definition of a “cigarette” in any
2 prior act of Congress or regulation. See Internal Revenue Code, 26 U.S.C. § 5702(c)
3 (defining “cigarette” as “(1) any roll of tobacco wrapped in paper or in any substance
4 not containing tobacco, and (2) any roll of tobacco wrapped in any substance
5 containing tobacco which, because of its appearance, the type of tobacco used in the
6 filler, or its packaging and labeling, is likely to be offered to, or purchased by,
7 consumers as a cigarette described in paragraph (1)”); 27 C.F.R. § 44.11 (defining
8 “cigarette” as “(a) Any roll of tobacco wrapped in paper or in any substance not
9 containing tobacco, and (b) Any roll of tobacco wrapped in any substance containing
10 tobacco which, because of its appearance, the type of tobacco used in the filler, or its
11 packaging and labeling, is likely to be offered to, or purchased by, consumers as a
12 cigarette described in paragraph (a) of this definition”); 27 C.F.R. § 40.11 (defining
13 “cigarette” as “(1) Any roll of tobacco wrapped in paper or in any substance not
14 containing tobacco, and (2) any roll of tobacco wrapped in any substance containing
15 tobacco which, because of its appearance, the type of tobacco used in the filler, or its
16 packaging and labeling, is likely to be offered to, or purchased by, consumers as a
17 cigarette described in paragraph (1) of this definition”). Flavored Paper does not fall
18 within the definition of cigarette under any statute or regulation.

19 15. The Act also states that “[t]he requirements applicable to cigarettes . . .
20 shall also apply to cigarette tobacco.” Pub. L. 111-31 § 900(4), 21 U.S.C. § 387(4).
21 The Act defines “Cigarette tobacco” as “any product that consists of loose tobacco that
22 is intended for use by consumers in a cigarette.” *Id.*

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The FDA's Unlawful Attempt to Regulate Flavored Paper

16. On September 14, 2009, the FDA issued a "Letter to Industry on Cigarettes Containing Certain Characterizing Flavors." This letter states that the special rule for cigarettes prohibiting "characterizing flavors" "applies to all tobacco products that meet the definition of a "cigarette" in section 900(3) of the Act even if they are not labeled as "cigarettes" or are labeled as cigars or as some other product." FDA, Letter to Industry on Cigarettes Containing Certain Characterizing Flavors, *available at:* <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm182186.htm> (last visited Oct. 1, 2009) (A true and correct copy of this letter is attached hereto as Exhibit "1".) Under the FDA's own letter, the ban on "characterizing flavors" applies only to cigarettes. Because flavored papers sold separately do not meet the definition of cigarette under the Act, they are not subject the ban on "characterizing flavors." See Pub. L. 111-31 § 900(3), 21 U.S.C. § 387(3).

17. On September 22, 2009, the FDA issued a guidance document titled "General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors" representing the FDA's "current thinking" on the Act's ban on cigarettes containing characterizing flavors. FDA, General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors, Sept. 22, 2009, *available at:* <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/FlavoredTobacco/ucm183228.htm> (last visited Oct. 1, 2009) ("Guidance Document") (A true and correct copy of the Guidance Document is attached hereto as Exhibit "2").

1 The Guidance Document states that the special rule for cigarettes in Section
2 907(a)(1)(A) of the Act also prohibits separately sold rolling paper intended for use in
3 roll-your-own cigarettes from containing an artificial or natural flavor. Guidance
4 Document, ¶ 4.

5 18. The FDA's conclusion that Flavored Paper sold separately are cigarettes
6 under the Act is not supported by the language of the Act or the definitions of
7 "cigarette" in the FCLAA, the Internal Revenue Code, or federal regulations.

8 19. Due to the FDA's position with regards to Flavored Paper, BBK has
9 discontinued sales of Flavored Paper for fear that the FDA intends to treat Flavored
10 Paper as cigarettes under the Act, prohibit the sale of Flavored Paper, and impose
11 civil and criminal penalties for the sale of Flavored Paper.

12 **BBK has been and will continue to be irreparably harmed**

13 20. In view of the FDA's intent to prosecute sellers of Flavored Paper, BBK
14 has had to discontinue its sales of Flavored Paper, which represents a significant
15 portion of BBK's sales and revenue.

16 21. The discontinuation of the sale of Flavored Paper has already had a
17 devastating impact on BBK's business and will irreparably harm BBK's reputation with
18 its customers and suppliers. BBK's retail customers have been returning to BBK tens
19 of thousands of dollars worth of Flavored Paper.

20 22. In addition, BBK has approximately \$750,000 of Flavored Paper
21 inventory which it will have no ability to re-sell if the FDA is permitted to ban the sale of
22 Flavored Paper.

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1 cigarette under the Act and, therefore, the Act's special rule for cigarettes prohibiting
2 "characterizing flavors" does not apply to Flavored Paper.

3 **COUNT II: DECLARATORY JUDGMENT (5 U.S.C. § 706(2)(C))**

4 29. BBK repeats and re-alleges each and every allegation set forth in
5 Paragraphs 1 through 28 as though more fully set forth at length herein.

6 30. The FDA has no authority under the Act to regulate products that are not
7 tobacco products.

8 31. The FDA has no authority under the Act to regulate any products except
9 "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" absent
10 the promulgation of regulations establishing such authority. The FDA has not
11 promulgated any regulations with respect to the Act and, based on the provisions of
12 the Act, cannot promulgate any such regulations.

13 32. Flavored Paper are neither cigarettes nor tobacco products under the
14 Act.

15 33. Therefore, the FDA's attempt to regulate flavored papers is "in excess of
16 statutory jurisdiction, authority, or limitations of statutory right." 5 U.S.C. § 706(2)(C).

17 34. The FDA's interpretation of the Act is also "arbitrary, capricious, an
18 abuse of discretion, [and] otherwise not in accordance with law." 5 U.S.C. § 706(2)(B).

19 35. By reason of the foregoing, BBK is entitled to judgment in its favor and
20 against Defendants declaring that the FDA has no authority to regulate Flavored
21 Paper under the Act.

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COUNT III: INJUNCTIVE RELIEF

36. Plaintiff repeats and re-alleges each and every allegation set forth in Paragraphs 1 through 35 as though more fully set forth at length herein.

37. BBK is likely to succeed on the merits of this dispute.

38. Due to the FDA’s attempted regulation and ban of Flavored Paper under the Act, BBK has and will continue to suffer irreparable harm for which there is no adequate remedy at law.

39. BBK therefore requests that this Court enter a temporary restraining order, preliminary injunction, and permanent injunction prohibiting the FDA from issuing statements to the tobacco industry or the public that Flavored Paper is prohibited by the Act, promulgating rules or regulations with respect to Flavored Paper, or taking any other action adverse to BBK with respect to Flavored Paper on the basis that Flavored Paper is prohibited by the Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, BBK TOBACCO & FOODS, LLP, an Arizona limited liability partnership, respectfully requests that this Court enter an order granting judgment in favor of Plaintiff and against Defendants:

- A. Declaring that Flavored Paper sold separately is not a tobacco product under the Act;
- B. Declaring that the Defendants have no authority to regulate Flavored Paper sold separately under the Act; and
- C. Entering a temporary restraining order, preliminary injunction, and permanent injunction prohibiting the Defendants from issuing statements to the

1 tobacco industry or the public that Flavored Paper sold separately is prohibited
2 by the Act, promulgating rules or regulations with respect to Flavored Paper
3 sold separately, or taking any other action adverse to BBK with respect to
4 Flavored Paper sold separately on the basis that Flavored Paper sold
5 separately is prohibited by the Act.

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7 RESPECTFULLY SUBMITTED this 7th day of October, 2009.

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LAKE & COBB, P.L.C.

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s/ Joel E. Sannes

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Joel E. Sannes

Attorneys for Plaintiff

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