

1 **WO**

2

3

4

5

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

6

7

8

BBK Tobacco & Foods, LLP,

No. CV 09-2111-PHX-JAT

9

Plaintiff,

**ORDER**

10

vs.

11

12

(1) U.S. Food and Drug Administration;  
(2) Margaret A. Hamburg, Commissioner  
of the United States Food and Drug  
Administration; (3) U.S. Departement of  
Health and Human Services; (4) Kathleen  
Sebelius, Secretary of the United States  
Department of Health and Human  
Services,

15

16

Defendants.

17

18

19

20

21

22

23

24

25

26

27

28

Pending before the Court is Plaintiff BBK Tobacco & Foods, LLP’s (“BBK”) Motion for Order to Show Cause re: Plaintiff’s Motion for Temporary Restraining Order and Preliminary Injunction (Doc. # 12); BBK’s Motion for Temporary Restraining Order and Preliminary Injunction (Doc. # 13); BBK’s Motion for Summary Judgment (Doc. # 34); and Defendants U.S. Food and Drug Administration (“FDA”), Margaret A. Hamburg, U.S. Departement of Health and Human Services, and Kathleen Sebelius (collectively “Defendants”) Opposition to Plaintiff’s Motion for Summary Judgment and Cross-Motion to Dismiss or in the Alternative for Summary Judgment (Doc. # 44). For the reasons that follow, the Court grants Defendants’ motion based upon Federal Rules of Civil Procedure 12(b)(1) and denies all other pending motions.

1 **BACKGROUND**

2 The following facts are not in dispute. BBK is in the business of distributing, among  
3 other things, various brands and flavors of flavored rolling papers to retailers. BBK’s  
4 flavored rolling papers are sold in separate packages apart from any tobacco product, and the  
5 flavored papers do not contain any tobacco. Nevertheless, BBK’s flavored papers are  
6 intended to be used by customers who use the papers to make “roll-your-own tobacco”  
7 cigarettes in addition to use for “non-tobacco smokable herbs.” (Doc. #35 at p. 3, ¶ 6.)

8 On June 22, 2009, the President signed into law the Family Smoking Prevention and  
9 Tobacco Control Act (“Tobacco Act”), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 21  
10 U.S.C. § 387 *et seq.*). The Tobacco Act includes a “Special rule for cigarettes,” wherein  
11 Congress prohibited cigarettes and their component parts from containing certain  
12 characterizing flavors:

13 Special rule for cigarettes

14 Beginning 3 months after June 22, 2009, a cigarette or any of its  
15 component parts (including the tobacco, filter, or paper) shall not contain, as  
16 a constituent (including a smoke constituent) or additive, an artificial or natural  
17 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.

18 21 U.S.C. § 387g(a)(1)(A). Among its express purposes, Congress sought to secure the  
19 FDA’s “authority to address issues of particular concern to public health officials, especially  
20 the use of tobacco by young people and dependence on tobacco.” 123 Stat. at 1781.

21 On September 14, the FDA issued a “Letter to Industry on Cigarettes Containing  
22 Certain Characterizing Flavors,” wherein the FDA stated that the special rule for cigarettes  
23 “applies to all tobacco products that meet the definition of a ‘cigarette’ in section 900(3) of  
24 the Act even if they are not labeled as ‘cigarettes’ or are labeled as cigars or as some other  
25 product.” (Doc. # 35-1 at p. 8.)

26 On September 22, the FDA posted “Form 3734” on its website related to “information  
27 regarding cigarettes with characterizing flavors.” (Doc. # 35-1 at p. 18.) The FDA states in  
28 its Form 3734 that “[e]ffective September 22, 2009, cigarettes and their components, such

1 as filters and papers, that contain certain characterizing flavors are considered adulterated  
2 under the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking  
3 Prevention and Tobacco Control Act.” (*Id.*) Form 3734 asks the user to input, among other  
4 things: a description of the product type, whether cigarette, filter, or paper; the characterizing  
5 flavor; a description of the purchase; and a description of the store or internet information  
6 where the items were purchased or discovered. (*Id.*)

7 Also on September 22, the FDA issued a guidance document entitled “General  
8 Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing  
9 Flavors” (“Q & A Guidance Document”). (Doc. # 35-1 at p. 19.) The FDA included the  
10 following question and answer in its Q & A Guidance Document:

11 Does the special rule for cigarettes in section 907(a)(1)(A) of the  
12 FDCA, banning cigarettes containing an artificial or natural flavor that is a  
13 characterizing flavor, apply to rolling paper or filters intended for use in roll-  
your-own cigarettes?

14 Yes. The special rule for cigarettes in section 907(a)(1)(A) of the  
15 FDCA prohibits the component parts of a cigarette (including the filter or  
16 paper) from containing an artificial or natural flavor that is a characterizing  
17 flavor. Section 900(3) of the FDCA defines “cigarette” as a tobacco product  
18 that “meets the definition of the term ‘cigarette’ under section 3(1) of the  
19 Federal Cigarette Labeling and Advertising Act,” which states that a cigarette  
is any wrapped roll of tobacco. A consumer rolled, roll-your-own cigarette is  
a cigarette under section 900(3) because it is a wrapped roll of tobacco.  
Rolling paper or filters intended for use in roll-your-own cigarettes are  
component parts of a rolled, roll-your-own cigarette and therefore may not be  
flavored with a characterizing flavor.

20 (*Id.* at p. 23, question 4.) The FDA also included the following disclaimer in its Q & A  
21 Guidance Document: “This guidance document represents the [FDA’s] current thinking on  
22 this topic. It does not create or confer any rights for or on any person and does not operate  
23 to bind FDA or the public.” (*Id.* at p. 21.)

24 In November 2009, the FDA issued a “Final guidance for Industry,” concerning  
25 “Listing of Ingredients in Tobacco Products.” (“Listing Guidance Document”) (Plaintiff’s  
26 trial ex.11 at p. 1.) The FDA included the following statements in its Listing Guidance  
27 Document:

1 FDA intends to use the following definitions in implementing the  
2 ingredient listing requirements of section 904 of the act:

3 . . . .

4 The term “tobacco product” . . . is not limited to products containing  
5 tobacco, but also includes components, parts, and accessories of tobacco  
6 products, whether they are sold for further manufacturing or for consumer use.  
7 For example, tobacco, papers, and filters are tobacco products, whether they  
8 are sold to consumers for use with roll-your-own tobacco or are sold for  
9 further manufacturing into a product sold to a consumer, such as a cigarette.

10 (*Id.* at pp. 3-4.) The FDA included a similar disclaimer as is contained in its Q & A  
11 Guidance Document: “This guidance represents the [FDA’s] current thinking on this topic.  
12 It does not create or confer any rights for or on any person and does not operate to bind FDA  
13 or the public.” (*Id.* at p. 2.)

14 In October 2009, BBK filed this present action seeking a declaration that its separately  
15 sold flavored rolling papers are not tobacco products under the Tobacco Act and, hence,  
16 Defendants have no authority to regulate separately sold flavored papers. BBK also seeks  
17 injunctive relief in the form of prohibiting Defendants from: issuing statements that  
18 separately sold flavored papers are prohibited by the Tobacco Act; promulgating rules or  
19 regulations to this effect; or taking any other adverse action towards BBK based upon  
20 flavored papers being prohibited by the Tobacco Act.

## 21 ANALYSIS

22 Both parties seek summary judgment under Rule 56. Defendants, however, also seek  
23 to dismiss BBK’s action pursuant to Rules 12(b)(1) and 12(b)(6). Because subject matter  
24 jurisdiction is a threshold issue, the Court will first address Defendants’ arguments under  
25 Rule 12(b)(1). *See Orient v. Linus Pauling Inst. of Sci. & Med.*, 936 F.Supp. 704, 706 (D.  
26 Ariz. 1996) (“Federal subject matter jurisdiction is a threshold issue that goes to the power  
27 of the court to hear the case . . .”).

### 28 *Subject Matter Jurisdiction*

“The party asserting jurisdiction has the burden of proving all jurisdictional facts.”  
*Indus. Tectonics, Inc. v. Aero Alloy*, 912 F.2d 1090, 1092 (9th Cir. 1990) (citing *McNutt v.*  
*Gen. Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936)). In effect, the Court presumes

1 lack of jurisdiction until the plaintiff proves otherwise. *Stock West, Inc. v. Confederated*  
2 *Tribes*, 873 F.2d 1221, 1225 (9th Cir. 1989). The defense of lack of subject matter  
3 jurisdiction may be raised at any time by the parties or the Court. *See* FED. R. CIV. P.  
4 12(h)(3).

#### 5 RIPENESS

6 Defendants argue that because they have not taken any enforcement action or any  
7 other final agency action with respect to flavored rolling papers, the doctrine of ripeness  
8 precludes this Court from exercising judicial review over BBK’s claims. “Ripeness is a  
9 justiciability doctrine designed ‘to prevent the courts, through avoidance of premature  
10 adjudication, from entangling themselves in abstract disagreements over administrative  
11 policies, and also to protect the agencies from judicial interference until an administrative  
12 decision has been formalized and its effects felt in a concrete way by the challenging  
13 parties.’” *Nat’l Park Hospitality Ass’n v. Dep’t. of Interior*, 538 U.S. 803, 807-08 (2003)  
14 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967), *overruled on other grounds*  
15 *by Califano v. Sanders*, 430 U.S. 99, 105 (1977)). Ripeness stems “both from Article III  
16 limitations on judicial power and from prudential reasons for refusing to exercise  
17 jurisdiction.” *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 57 n. 18 (1993).  
18 Determining whether administrative action is ripe for judicial review requires the Court “to  
19 evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties  
20 of withholding court consideration.” *Nat’l Park*, 538 U.S. at 808 (citing *Abbott Labs.*, 387  
21 U.S. at 149).

#### 22 **Fitness**

23 A claim is fit for review by this Court if the issues raised are primarily legal and the  
24 administrative action is final. *State of Cal., Dept. of Educ. v. Bennett*, 833 F.2d 827, 833 (9th  
25 Cir. 1987). The FDA argues that there are factual issues integral to BBK’s claims, whereas  
26 BBK argues that the crux of the primary issue presented to the Court—whether the Tobacco  
27 Act grants the FDA the authority to regulate separately sold flavored rolling papers—is in  
28 essence a legal question. It is not clear, from the plain language of the Tobacco Act, whether

1 the Court would be required to engage in a fact-finding exercise before being able to properly  
2 address the legal issues presented by BBK. For example, it is not clear to what extent the  
3 Court would be required to determine whether the flavored rolling papers impart a  
4 “characterizing flavor,” within the meaning of the Tobacco Act. Nevertheless, even  
5 assuming the issues raised are primarily legal, based upon the record currently before the  
6 Court, the complained of administrative action is not final.

7 “The requirement of finality is interpreted pragmatically. A court looks to whether  
8 the agency action represents the final administrative word to insure that judicial review will  
9 not interfere with the agency’s decision-making process.” *Id.* (internal citations omitted).  
10 In this case, the FDA has not promulgated a final rule or regulation with respect to the  
11 applicability of the Tobacco Act to separately sold flavored rolling papers. Indeed, the FDA  
12 has not issued any regulations under the Tobacco Act, much less regulations specifically  
13 addressing flavored rolling paper. Moreover, the FDA has not taken any enforcement actions  
14 with respect to companies, including BBK, that produce flavored rolling papers. Nor has the  
15 FDA taken the lesser action of issuing a warning letter to BBK or to other similar companies  
16 currently selling flavored rolling papers in the United States. *See Lujan v. Nat’l Wildlife*  
17 *Fed’n*, 497 U.S. 871, 891 (1990) (controversy concerning a regulation is not ordinarily ripe  
18 for review until the regulation has been applied to the claimant’s situation by some concrete  
19 action). In fact, the FDA has not taken any specific action with regard to BBK.

20 The only action taken by the FDA with respect to flavored rolling papers is the FDA’s  
21 statements as contained in its Q & A Guidance Document and its Listing Guidance  
22 Document. The pertinent statements contained in its Q & A Guidance Document are as  
23 follows:

24 Does the special rule for cigarettes in section 907(a)(1)(A) of the  
25 FDCA, banning cigarettes containing an artificial or natural flavor that is a  
26 characterizing flavor, apply to rolling paper or filters intended for use in roll-  
your-own cigarettes?

27 Yes. The special rule for cigarettes in section 907(a)(1)(A) of the  
28 FDCA prohibits the component parts of a cigarette (including the filter or  
paper) from containing an artificial or natural flavor that is a characterizing  
flavor. Section 900(3) of the FDCA defines “cigarette” as a tobacco product

1 that “meets the definition of the term ‘cigarette’ under section 3(1) of the  
2 Federal Cigarette Labeling and Advertising Act,” which states that a cigarette  
3 is any wrapped roll of tobacco. A consumer rolled, roll-your-own cigarette is  
4 a cigarette under section 900(3) because it is a wrapped roll of tobacco.  
5 Rolling paper or filters intended for use in roll-your-own cigarettes are  
6 component parts of a rolled, roll-your-own cigarette and therefore may not be  
7 flavored with a characterizing flavor.

8 (Doc. # 35-1 at p. 23, question 4.) The pertinent statements contained in the FDA’s Listing  
9 Guidance Document are as follows:

10 FDA intends to use the following definitions in implementing the  
11 ingredient listing requirements of section 904 of the act:

12 . . . .

13 The term “tobacco product” . . . is not limited to products containing  
14 tobacco, but also includes components, parts, and accessories of tobacco  
15 products, whether they are sold for further manufacturing or for consumer use.  
16 For example, tobacco, papers, and filters are tobacco products, whether they  
17 are sold to consumers for use with roll-your-own tobacco or are sold for  
18 further manufacturing into a product sold to a consumer, such as a cigarette.

19 (Plaintiff’s trial ex.11 at p. 3-4.) It is not entirely clear from these statements that the FDA  
20 is actually interpreting the Tobacco Act in such a manner as to preclude the sale of *separately*  
21 *sold* flavored rolling papers. Nevertheless, even assuming these statements by the FDA in  
22 its guidance documents apply to separately sold flavored rolling papers, such statements fail  
23 as final agency action within the meaning of the ripeness inquiry.

24 Any action taken against BBK, or any other such company, cannot be premised upon  
25 the FDA’s guidance documents—regardless of whether the documents are stamped as “final”  
26 or “draft.” That is, the FDA’s guidance documents do not provide any legal basis from  
27 which the FDA can institute civil or criminal legal proceedings. The FDA can only premise  
28 such proceedings upon the Tobacco Act itself, or regulations the FDA publishes under the  
Tobacco Act—none of which yet exist. One of the hallmarks of finality in this context is  
whether “legal consequences will flow” from the agency’s actions. *Bennett v. Spear*, 520  
U.S. 154, 178 (1997). No such “legal consequences” can flow from the FDA’s Q & A  
Guidance Document, nor its Listing Guidance Document. As such, the FDA’s guidance  
documents do not constitute final agency action within the meaning of the ripeness inquiry.

1           Moreover, in each of the guidance documents, the FDA included the following  
2 disclaimer: “This guidance document represents the [FDA’s] current thinking on this topic.  
3 It does not create or confer any rights for or on any person and does not operate to bind FDA  
4 or the public.” (*Id.* at p. 21.) It is clear that the guidance documents, which represent only  
5 the FDA’s “current thinking,” do not constitute the final administrative word such that  
6 BBK’s claims are ripe for judicial review. *Franklin v. Massachusetts*, 505 U.S. 788, 797  
7 (1992) (stating that an agency action is “not final” if it is only “tentative”). Viewed  
8 pragmatically, the FDA is free to abandon its “current thinking” on the question of flavored  
9 rolling papers at any stage in the administrative process before issuing its final regulations  
10 under the Tobacco Act, or taking any other administration actions. “A claim is not ripe for  
11 adjudication if it rests upon ‘contingent future events that may not occur as anticipated, or  
12 indeed may not occur at all.’” *Texas v. United States*, 523 U.S. 296, 300 (1998) (quoting  
13 *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-81 (1985) (internal quotation  
14 omitted)). In essence, BBK seeks an advisory opinion from this Court: *If* the FDA  
15 determines that its current interpretation of the Tobacco Act as contained in its guidance  
16 documents and other statements should constitute its final interpretation, *then* the Court  
17 should find that the FDA exceeded its authority under the Tobacco Act . Article III courts,  
18 however, are not in the business of resolving *if-then* hypotheticals, especially in the context  
19 of administrative agencies. *Cf. Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013-14 (9th Cir.  
20 1987) (distinguishing a substantive rule from a “general statement of policy,” and stating that  
21 “parties can challenge the policy determinations made by the agency only if and when the  
22 directive has been applied specifically to them”).

23           Accordingly, because there has been no final action by the FDA under the Tobacco  
24 Act, the issues presented by BBK are not fit for judicial review.<sup>1</sup>

---

25  
26           <sup>1</sup> BBK also complains of the statements issued by the FDA in its Letter to Industry,  
27 Form 3734, and in certain comments made to the media by the Director for the Center for  
28 Tobacco Products. However, each of these statements suffer from the same infirmities as the  
guidance documents; namely, they do not represent the final word with respect to the FDA’s



1 **Hardship**

2 Even if the Court were persuaded that the issues presented by BBK were fit for  
3 judicial review, BBK has failed to demonstrate the required hardship that would result from  
4 the Court’s withholding consideration of BBK’s claims. The Ninth Circuit has repeatedly  
5 held that “that the hardship element of the *Abbott Labs* standard is not met unless a litigant  
6 shows that withholding review would result in ‘direct and immediate’ hardship and would  
7 entail *more than possible financial loss.*” *Principal Life Ins. Co. v. Robinson*, 394 F.3d 665,  
8 670 (9th Cir. 2005) (emphasis added) (quoting *W. Oil & Gas Ass’n v. Sonoma County*, 905  
9 F.2d 1287, 1291 (9th Cir. 1990) (internal quotation marks omitted). The “direct and  
10 immediate” hardship presented by BBK primarily involves financial loss: it is unable to sell  
11 its current flavored paper inventory; it is contractually obligated to continue to purchase  
12 flavored paper from its exclusive supplier; it would be obligated to institute layoffs within  
13 its company; it is losing valuable shelf-space that affects its continuing sales; and its  
14 reputation in the business community is suffering, which in turn affects its sales. While the  
15 Court does not discount the reality of BBK’s claims, such claims of possible financial loss  
16 are insufficient under Ninth Circuit precedent to establish ripeness. *See Bennet*, 833 F.2d at  
17 834 (“The accrual of interest poses a ‘direct and immediate’ threat to California by making  
18 delay of payment more costly. However, the harm that is presaged is limited to financial  
19 expense. This is an insufficient showing of hardship to justify pre-enforcement judicial  
20 review. Hence, California’s claim contesting the assessment of prejudgment interest is not  
21 ripe.”).

22 Moreover, based upon the evidence BBK submitted of its hardship, such hardship  
23 stems not from final agency action, but rather BBK’s own decision to discontinue the sale  
24 and distribution of its separately sold flavored rolling papers. The FDA has not taken any  
25 specific action with respect to BBK or any of its products—the FDA has not filed an  
26 \_\_\_\_\_  
27 stance on separately sold flavored rolling papers, nor do any legal consequence flow from  
28 such statements. Hence, such statements and documents are insufficient in conferring a ripe  
issue for this Court’s consideration.



1 administrative agency to perform functions within its special competence—to make a factual  
2 record, to apply its expertise, and to correct its own errors so as to moot judicial  
3 controversies.” *Parisi v. Davidson*, 405 U.S. 34, 37 (1972).

4 The FDA contends that BBK can exhaust its administrative remedies by filing a  
5 “citizen petition” asking the FDA for a formal determination of whether the Tobacco Act  
6 applies to BBK’s flavored rolling papers. 21 C.F.R. §§ 10.25(a), 10.30 (1990). BBK does  
7 not dispute that it did not exhaust its administrative remedies prior to the filing of this action,  
8 nor does BBK dispute that the filing of a citizen petition was an available avenue from which  
9 it could have proceeded. Nevertheless, BBK claims that the filing of such a petition was not  
10 required in this case.

11 BBK argues that it should not be required to exhaust its available administrative  
12 remedies because doing so would cause BBK irreparable harm. Irreparable harm can be an  
13 exception to the requirement of administrative exhaustion. *See Bd. of Trs. of Const.*  
14 *Laborers’ Pension Trust for S. California v. M.M. Sundt Const. Co.*, 37 F.3d 1419, 1421 (9th  
15 Cir. 1994) (“Exceptions to exhaustion requirements are usually limited, and apply only in  
16 extraordinary circumstances, such as, when the arbitral process would be futile or would  
17 cause the plaintiff irreparable injury.”). Notwithstanding, BBK has failed to demonstrate that  
18 requiring it to pursue its available administrative remedies would cause it irreparable harm.  
19 Again, the irreparable harm alleged by BBK primarily amounts to financial loss. Moreover,  
20 the Tobacco Act was signed into law in June 2009. Rather than pursue a citizen petition  
21 through the FDA, BBK decided to wait nearly four months and file an action directly with  
22 this Court. As described above, BBK’s decision to discontinue the distribution of its  
23 products stems from its own decisions, not any final actions taken by the FDA. While BBK  
24 faces a threat of real financial loss, this alone does not relieve BBK from the requirement of  
25 pursuing its administrative remedies, especially after waiting idly for several months before  
26 taking action, and especially when such financial loss stems primarily from BBK’s own  
27 volition. The Court does not discount Mr. Kesselman’s past experiences with the criminal  
28 justice system and how such experiences affect his current decisions concerning BBK’s

1 continued distribution of flavored rolling papers in wake of the Tobacco Act. Nevertheless,  
2 BBK has failed to demonstrate that irreparable harm, to the extent it exists here, is resulting  
3 from the FDA's actions, and not the actions of BBK alone, such that BBK should not be  
4 compelled to exhaust its available administrative remedies.

5 Therefore, the Court finds that BBK's failure to exhaust its administrative remedies  
6 provides additional grounds for dismissing BBK's claims.

7 **CONCLUSION**

8 Having evaluated the fitness of the issues for judicial decision and the hardship to  
9 BBK of withholding consideration, the Court concludes that the issues presented are not ripe  
10 for judicial review. Moreover, BBK's failure to exhaust its administrative remedies also  
11 obligates this Court to dismiss BBK's claims. Because the Court finds that dismissal is  
12 appropriate under Rule 12(b)(1), the Court need not visit Defendants' other proffered reasons  
13 for dismissal. Likewise, the Court does not reach the question of whether the Tobacco Act  
14 applies to separately sold flavored rolling papers as discussed in the parties' cross-motions  
15 for summary judgment and as presented in the trial to the bench.

16 Accordingly,

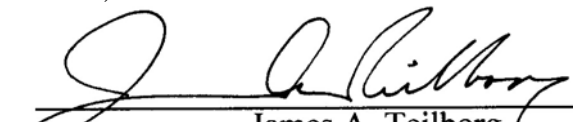
17 **IT IS ORDERED** that Defendants' Opposition to Plaintiff's Motion for Summary  
18 Judgment and Cross-Motion to Dismiss or in the Alternative for Summary Judgment (Doc.  
19 # 44) is granted in so far as it is premised upon Federal Rules of Civil Procedure 12(b)(1).

20 **IT IS FURTHER ORDERED** that Plaintiff's Motion for Temporary Restraining  
21 Order and Preliminary Injunction (Doc. # 12) is denied.

22 **IT IS FURTHER ORDERED** that BBK's Motion for Temporary Restraining Order  
23 and Preliminary Injunction (Doc. # 13) is denied.

24 **IT IS FINALLY ORDERED** that BBK's Motion for Summary Judgment (Doc. #  
25 34) is denied.

26 DATED this 8<sup>th</sup> day of December, 2009.

27   
28 \_\_\_\_\_  
James A. Teilborg  
United States District Judge