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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

BBK Tobacco & Foods, LLP, Plaintiff, vs. (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, Defendants.	No. CV 09-2111-PHX-JAT **ORDER**

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.

BACKGROUND

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

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

> Special rule for cigarettes
>
> Beginning 3 months after June 22, 2009, a cigarette or any of its component parts (including the tobacco, filter, or 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 U.S.C. § 387g(a)(1)(A). Among its express purposes, Congress sought to secure the FDA's "authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." 123 Stat. at 1781.

On September 14, the FDA issued a "Letter to Industry on Cigarettes Containing Certain Characterizing Flavors," wherein the FDA stated that the special rule for cigarettes "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." (Doc. # 35-1 at p. 8.)

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

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

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

> Does the special rule for cigarettes in section 907(a)(1)(A) of the FDCA, banning cigarettes containing an artificial or natural flavor that is a characterizing flavor, apply to rolling paper or filters intended for use in roll-your-own cigarettes?
>
> Yes. The special rule for cigarettes in section 907(a)(1)(A) of the 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 that "meets the definition of the term 'cigarette' under section 3(1) of the 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.

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

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

> FDA intends to use the following definitions in implementing the ingredient listing requirements of section 904 of the act:
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> . . . .
>
> The term "tobacco product" . . . is not limited to products containing tobacco, but also includes components, parts, and accessories of tobacco products, whether they are sold for further manufacturing or for consumer use. For example, tobacco, papers, and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

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

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

ANALYSIS

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

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

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

RIPENESS

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

Fitness

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

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

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

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

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

> that "meets the definition of the term 'cigarette' under section 3(1) of the 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.

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

> FDA intends to use the following definitions in implementing the ingredient listing requirements of section 904 of the act:
>
> . . . .
>
> The term "tobacco product" . . . is not limited to products containing tobacco, but also includes components, parts, and accessories of tobacco products, whether they are sold for further manufacturing or for consumer use. For example, tobacco, papers, and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

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

Any action taken against BBK, or any other such company, cannot be premised upon the FDA's guidance documents–regardless of whether the documents are stamped as "final" or "draft." That is, the FDA's guidance documents do not provide any legal basis from which the FDA can institute civil or criminal legal proceedings. The FDA can only premise 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.

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

Accordingly, because there has been no final action by the FDA under the Tobacco Act, the issues presented by BBK are not fit for judicial review.[1]

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[1] BBK also complains of the statements issued by the FDA in its Letter to Industry, Form 3734, and in certain comments made to the media by the Director for the Center for 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

Hardship

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

Moreover, based upon the evidence BBK submitted of its hardship, such hardship stems not from final agency action, but rather BBK's own decision to discontinue the sale and distribution of its separately sold flavored rolling papers. The FDA has not taken any specific action with respect to BBK or any of its products–the FDA has not filed an

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stance on separately sold flavored rolling papers, nor do any legal consequence flow from such statements. Hence, such statements and documents are insufficient in conferring a ripe issue for this Court's consideration.

enforcement action, the FDA has not sought civil or criminal remedies against BBK, nor has the FDA even sent BBK a warning letter concerning BBK's products. In short, the FDA has not informed BBK that BBK's complained of products are unlawful under the Tobacco Act. BBK's decision to stop distributing flavored rolling papers is not in response to any final agency action, but rather BBK's own volition and interpretation of the Tobacco Act.[2] BBK refrained from distributing flavored rolling papers upon the effective date of the Tobacco Act without seeking any input from the FDA concerning the lawfulness of BBK's products–even though such input could have been sought through, for example, the filing of a citizens petition. In addition to the requirement that BBK suffer more than financial loss, BBK has failed to demonstrate a direct and immediate hardship stemming from the actions of the FDA.

Therefore, after having evaluated the fitness of the issues for judicial decision and the hardship to BBK of withholding consideration, the Court finds that the issues presented are not ripe for judicial review. "[T]he presumption of available judicial review is subject to an implicit limitation: injunctive and declaratory judgment remedies, what the respondents seek here, are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy ripe for judicial resolution . . . ." *Reno*, 509 U.S. at 57 (internal quotations omitted) (quoting *Abbott Labs.*, 387 U.S. at 148).

EXHAUSTION

The Administrative Procedure Act provides for judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. "That section means that when a statute or agency rule dictates that exhaustion of administrative remedies is required, the federal courts may not assert jurisdiction to review agency action until the administrative appeals are complete." *White Mountain Apache Tribe v. Hodel,* 840 F.2d 675, 677 (9th Cir. 1988). The primary purpose of the exhaustion requirement "is to allow an

[2] The Court recognizes that certain of BBK's customers returned BBK's products without BBK prompting or directing such customers to do so. Again, the actions of BBK's customers, however, do not stem from final agency action.

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

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

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

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

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

CONCLUSION

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

Accordingly,

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

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

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

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

DATED this 8th day of December, 2009.

James A. Teilborg
United States District Judge