SMARTT
COALITION

February 18, 2010

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Request for Comments on the Use of Tobacco Marketing Descriptors to Convey Modified Risk; FDA Docket No. FDA-2010-N-0020

Dear Sir or Madam:

The Small Manufacturers Association for the Reasonable Treatment of Tobacco ("SMARTT") submits the following comments to the above-referenced docket. As noted in our prior correspondence, SMARTT is a coalition of Subsequent Participating Manufacturers ("SPMs") to the multi-state Master Settlement Agreement ("MSA"). We are now cooperating with one another with respect to issues associated with implementation of the Family Smoking Prevention and Tobacco Control Act (the "Act"), and appreciate this opportunity to comment on issues that are of common concern for the members of SMARTT.

Specifically, we write in response to a request for comments made by FDA on January 19, 2010 regarding the use of tobacco marketing descriptors to convey modified risk.[1] Section 911(b) of the Act prohibits, as of June 22, 2010 the manufacture of any tobacco product the label, labeling or advertising of which uses the descriptors "light," "mild," or "low" or similar descriptors (collectively, "modified risk descriptors"). At this time, the Agency is seeking comments on the types of descriptors that may be considered "similar" to the enumerated modified risk descriptors prohibited by the Act. In its request for comments, FDA proposes that such descriptors may include the use of colors. As illustrated below, the use of colors is unassociated with the relative risk of different tobacco products and should not be prohibited under Section 911(b).

Moreover, SMARTT anticipates that once FDA reviews the comments received in response to the above request, the Agency will issue a draft guidance regarding modified risk descriptors, providing another opportunity to comment before issuing a final guidance clarifying FDA's interpretation of the restrictions contained in Section 911(b). We note that it will be impossible for tobacco product manufacturers to adopt FDA's recommendations (as set forth in a final guidance) prior to June 22, 2010. Indeed, due to the long lead times required for revising

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[1] 75 Fed. Reg. 2879 (Jan. 19, 2010).

product packaging, tobacco product manufacturers were required to make decisions regarding new labeling as required by Section 911(b) for the post-June 22, 2010 period several months ago. Manufacturers, and especially small manufacturers, must generally initiate the process of altering product packaging up to a year in advance of introduction into commerce, and require long lead times to revise packaging and labeling materials and to obtain the requisite federal and state approvals for these revised materials. As such, the lack of certainty with respect to modified risk descriptor and other labeling requirements set to become effective on June 22, 2010 is a critical business issue of immediate and urgent importance to the Coalition. Due to the impossibility of amending labeling to account for any new statutory interpretations that FDA may set forth in interpretive guidance by June 22, 2010, we believe it is essential that FDA provide for enforcement discretion until at least nine (9) to twelve (12) months after the issuance of a final guidance clarifying the Agency's position with respect to modified risk descriptors – i.e. until such time as manufacturers are actually able to adopt labeling consistent with the recommendations to be set forth by FDA. Indeed, the statute itself reflects an understanding of the long lead times required, recognizing that tobacco product manufacturers needed 12 months (enactment on June 22, 2009 to effective date on June 22, 2010) to cease the use of the terms "light," "mild," and "low." Any other change to product packaging will require a similar timeframe for manufacturers to implement.

Further, proper enforcement by states, consistent with the intent of the Act and FDA's implementing guidance, is of equal importance to tobacco product manufacturers. We urge FDA to take appropriate measures to ensure that states are clearly informed of the meaning of sell through provisions and other aspects associated with the labeling requirements set to become effective in June. We appreciate this opportunity to comment and strongly urge FDA to exercise enforcement discretion and coordinate with the states accordingly.

I. The Use of Colors Does Not Impact Consumer Perceptions of Modified Risk and is Protected by Manufacturers' First Amendment Right to Differentiate Products

As with any product, different consumers quite simply have different tastes and preferences. Accordingly, many tobacco product manufacturers sell several different products within each brand family that have different tastes and provide different smoking experiences. Historically, these variants have been identified through the use of colors or terms that convey information related to product characteristics, formulation or style – *not* the relative health risks associated with the product. The use of colors communicates important information about these differing products to consumers. Indeed, the Supreme Court has recognized that tobacco product manufacturers have a First Amendment right to convey such information stating that "the tobacco industry has a protected interest in communicating information about its products and adult consumers have an interest in receiving that information."[2]

We note that several members of the SMARTT Coalition, including Nat Sherman, Commonwealth Brands, Inc. and Japan Tobacco International, are also filing comments to the

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[2] *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001).

above-referenced docket outlining, among other things, the reasons why the use of colors should not be considered "similar descriptors" nor banned under Section 911(b). We additionally incorporate those comments herein by reference.

II. The Complex Set of Existing Federal and State Labeling Requirements Precludes Compliance with New FDA Labeling Restrictions by June 22, 2010

In issuing guidance that impacts tobacco product labeling, FDA must account for the various other approvals and certifications that tobacco product manufacturers are required to obtain before they may lawfully circulate revised labeling in commerce. Complying with these overlapping and potentially conflicting approval and certification requirements imposed by states and other federal regulatory bodies takes several months to complete. In addition, tobacco product manufacturers face significant technical barriers to rapidly deploying revised product packaging, which adds to the long lead times required to implement any new labeling requirements. A diagram outlining the multiple steps involved in any tobacco product packaging revision is appended hereto as Attachment A. As this diagram illustrates, the reality of the timelines imposed by these multiple administrative requirements and technical challenges is that tobacco product manufacturers were required to commit to revised product packaging months ago in order to meet the June 22, 2010 deadline.[3] Absent FDA guidance on the meaning of "similar descriptors," tobacco product manufacturers had to base such revisions off a reasonable interpretation of Section 911(b). In the event that FDA issues an interpretation of Section 911(b) that runs counter to or otherwise expands or significantly changes existing decisions, FDA must be cognizant of the administrative and technical requirements involved and account for these required lead times in its enforcement policies.

Once a tobacco product manufacturer undertakes to revise product labeling, as may be required by new and forthcoming FDA interpretations of the Act, they must contend with significant technical barriers to implementing revised labeling. First, once FDA issues a new interpretation of the Act's labeling requirements, manufacturers must develop revised packaging artwork and labeling accordingly. These materials are typically developed by an outside agency and it can take up to four (4) weeks to complete. After final packaging artwork is developed and approved internally, it must be sent to a cylinder maker for engraving. The average time it takes to cut new cylinders is four (4) to five (5) weeks. Notably, FTC (described below) will only approve printed packages as proposed for distribution, as opposed to mock ups of the proposed artwork. Thus, tobacco product manufacturers must print (or request an outside vendor to print) a limited run of proposed packaging for submission to the FTC. For obvious reasons, full scale printing of revised packaging for manufacturing and subsequent distribution cannot begin until after the aforementioned approvals are received.

As indicated above, the approval and certification requirements associated with revising tobacco product packaging are extensive and time consuming to fulfill. Once a tobacco product manufacturer has produced a limited run of product labeling revised according to FDA

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[3] Indeed, many members of the SMARTT Coalition initiated the packaging revision process in October of 2009.

requirements, the manufacturer must **then** seek approval from multiple authorities, including the Federal Trade Commission ("FTC") and the fifty states. Specifically, tobacco product manufacturers must first obtain renewed FTC approval for any changes to product packaging.[4] Such approval is a legal prerequisite for state MSA certification and, as a practical matter, is necessarily predicate to filing for state fire safe certifications (both described below). Tobacco product manufacturers, especially small manufacturers, must await FTC packaging approval before undertaking the required state-level filings, as doing otherwise risks incurring additional costs in the form of duplicative filing fees should FTC require further packaging changes. It can take the FTC up to four (4) months to review and approve new labeling. This timeline, however, could be extended even further in the event that FDA guidance requires widespread labeling revisions throughout the industry, causing the FTC to be inundated with applications.

Once a manufacturer obtains FTC approval it then must pursue the other approvals required prior to distribution, including renewed state fire safe certifications from each state in which it intends to market its product.[5] Fire safe certifications are required in forty-three (43) states, as well as the District of Columbia. Six (6) other states will implement fire safe certification requirements by January 1, 2011. The timeframe for approval varies by state, however it can take up to three (3) months to obtain all required fire safe certifications.

Signatories of the MSA (as members of the SMARTT Coalition are) must additionally obtain new MSA certifications for any revised labeling.[6] States typically require the following packaging/product information, each of which have their own associated timelines, before they will issue MSA certification: documentation of (1) listing by the National Association of Attorneys General; (2) FTC approval; (3) CDC compliance with ingredient listing requirements[7]; and (4) state fire safe certification. The timeframe for approval varies by state, however it can sometimes take over three (3) months to obtain certification from all relevant states.[8]

Once manufacturers have completed this extensive and lengthy process, those that import products must next submit evidence of the required approvals and certifications to customs officials before products bearing revised labeling may be shipped. As noted above, many of these requirements are predicate to others, rendering the steps in the process sequential versus simultaneous and thereby extending the time that it takes tobacco product manufacturers to secure and align all of the approvals necessary for revising tobacco product packaging.

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4 *See* 15 U.S.C. § 1333(c).

5 *See e.g.* CAL. HEALTH & SAFETY CODE § 14950; N.Y. EXEC. 156-c; 425 ILL. COMP. STAT. 8/30.

6 *See e.g.* State of Kansas, Office of Attorney General, Participating Manufacturer Certification Form appended as Attachment B.

7 Tobacco product manufacturers are required to annually submit to CDC a listing of ingredients in their products. *See* 15 U.S.C. § 1335a(a). Upon receipt of satisfactory submissions, CDC will issue a letter confirming that the manufacturer is in compliance with the statutory requirement. It can take up to two (2) months for CDC to issue a compliance letter following receipt of an ingredient listing submission.

8 Indeed, in one instance it took nine (9) months for a member of SMARTT to receive all MSA certifications.

Once such approvals and certifications are in hand, tobacco product manufacturers must then schedule print runs. It takes an average of four (4) weeks to print packaging, and can take longer for small manufacturers, who typically do not possess in-house printing capabilities and must order packaging supplies in bulk to meet minimum print runs.[9] Globally speaking, the times noted for these various technical steps are "average" and will vary depending on a number of factors, many of which are beyond tobacco product manufacturers' control. For example, the above illustration assumes that the cylinder maker can begin engraving and the printer begin printing as soon as an order is received. However, similar to the backlog that new FDA interpretations may create at FTC, these vendors may be at capacity processing revised product labeling and, as such, may take significantly longer to complete orders. In addition to these timelines, tobacco product manufacturers also typically notify wholesale trade (distributors and retailers) of a packaging change up to three (3) months prior to introduction.

We reiterate that the cumulative result of the timelines imposed by these multiple administrative requirements and technical challenges is that tobacco product manufacturers were required to commit to revised product packaging months ago in order to meet the June 22, 2010 deadline. As a result, it will be impossible for manufacturers to comply with any new packaging restrictions that the FDA may announce in forthcoming guidance on Section 911(b), and to obtain the requisite approvals and certifications listed above by June 22, 2010. We therefore strongly urge FDA to exercise enforcement discretion in its implementation of packaging restrictions until at least nine (9) to twelve (12) months after the issuance of a final guidance clarifying the Agency's position with respect to modified risk descriptors. Such enforcement discretion would be consistent with the Act, which gave tobacco product manufacturers twelve (12) months to implement other packaging changes.

II. FDA Should Ensure That States Clearly Understand Labeling Restrictions and Accompanying Sell-Through Provisions

The activities that states undertake to enforce the Act are of equal practical importance to tobacco product manufacturers as the interpretive and enforcement activities of the FDA. Tobacco product manufacturers are vulnerable to overreaching by state-level authorities, especially to the extent that states' enforcement policies amount to interpretations that are inconsistent with FDA's own policies. Despite language in the Act establishing FDA as the principal authority for enforcement of the Act's requirements, it has been SMARTT's experience that state authorities have aggressively pursued enforcement against tobacco manufacturers and retailers. For example, notwithstanding guidance from FDA with respect to the ban on characterizing flavors, several states required the removal of non-violative products from retailers' shelves at unwarranted expense to tobacco product manufacturers operating in full compliance with the Act. We fear that the upcoming prohibition on the use of modified risk descriptors is another area ripe for overreaching by state authorities. As such, we underscore the importance of FDA establishing itself as the primary authority for implementation and

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[9] Small manufacturers must typically order six (6) to twelve (12) months supply at a time.

enforcement of the Act and further urge FDA to adequately inform states of the precise contours and scope of Section 911(b) restrictions and requirements.

As part of this necessary inter-governmental coordination and information effort, it is critically important that FDA clarify for states the meaning of sell-through provisions. Section 911(b)(3) provides that the effective date of the modified risk descriptor restrictions "shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with [this provision]." Accordingly, FDA should ensure that states understand that products which were manufactured prior to the effective date of Section 911(b) and introduced into the domestic commerce by the manufacturer within thirty (30) days thereafter are not subject to 911(b) restrictions and may continue to be sold by wholesalers and retailers. If states inappropriately seek to enforce Section 911(b) in relation to this legal product, it will nullify the protections that Congress intended to afford wholesalers and retailers in this sell-through provision. This will likely result in large scale returns of legal product, and tobacco product manufacturers, particularly small businesses, will be unfairly penalized and subject to unduly burdensome costs that may jeopardize their financial stability.

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We appreciate your consideration of the comments and recommendations set forth herein, and urge FDA to take measures, as well as exercise enforcement discretion accordingly.

Respectfully,

Bhavani Parameswar
President
King Maker Marketing Inc.

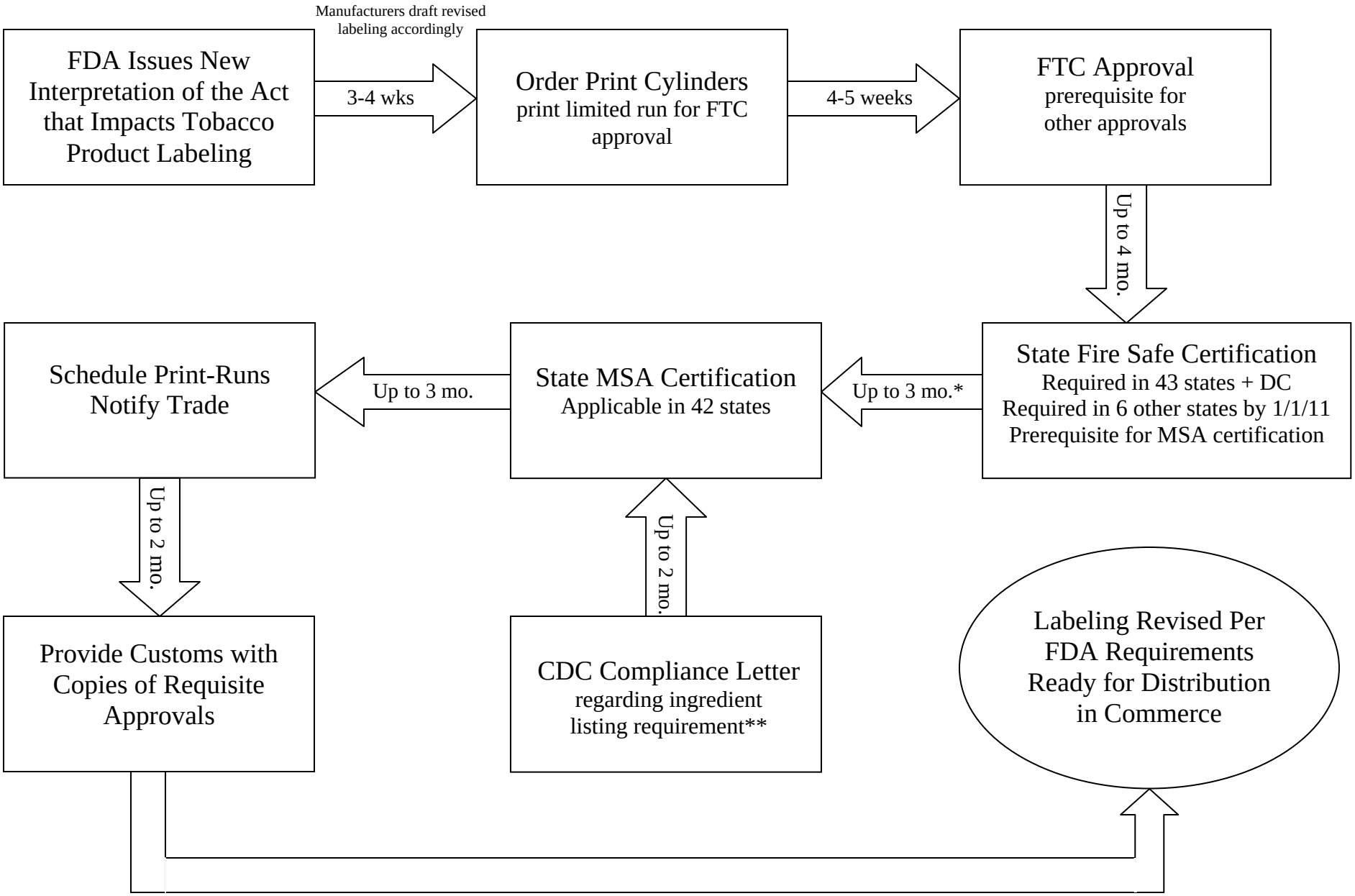
Anthony Hemsley
Vice President of Government Relations and Corporate Affairs
Commonwealth Brands, Inc.

Thomas Hirshfield
Director, Corporate Affairs & Communications
Japan Tobacco International

William Sherman
Executive Vice President
Sherman's 1400 Broadway NYC, Ltd.

Attachment A

Overall Time Required to Implement FDA Requirements for Tobacco Product Labeling is Up to One Year



* In one instance, it took over 9 months to obtain MSA certification from all 50 states

** CDC compliance letter can be pursued independent of packaging approval process, but is a prerequisite for MSA certification and is among the approvals that must be documented for customs.

Attachment B

OFFICE OF THE KANSAS ATTORNEY GENERAL

PARTICIPATING MANUFACTURER CERTIFICATION FORM

REVISED JANUARY 19, 2010

TYPE OF CERTIFICATION

This certification is: ☐ Initial ☐ Supplemental ☐ Renewal

MANUFACTURER INFORMATION

Manufacturer: _____

Mailing Address: _____

_____

Street Address: _____

_____

Note: The street address should be the physical location of the manufacturing plant.

Phone Number: _____ Fax Number: _____

E-Mail Address: _____

Website: _____

Federal Taxpayer ID Number: _____

Note: Only applies if manufacturer is registered in the United States.

IMPORTER INFORMATION

Note: Complete this section only if you are a manufacturer located outside of the United States.

Importer Name: _____

Contact Name:
and Title: _____

Mailing Address: _____

_____

Phone Number: _____ Fax Number: _____

E-Mail Address: _____

Federal Taxpayer
ID Number: _____

DESIGNATED CONTACT

Identify the person that you wish to receive all correspondence and official notifications. *Note: Failure to designate an official contact person will result in an incomplete certification.*

Contact Name: _____

Organization: _____

Relationship to
Manufacturer: _____
For example: Attorney, Importer, Tax Compliance Manager, etc.

Mailing Address: _____

_____

Phone Number: _____ Fax Number: _____

E-Mail Address: _____

BRAND FAMILIES TO BE CERTIFIED

Complete this page for each brand family you wish to certify for sale in Kansas. Only list **one** brand family per sheet. Attach additional sheet(s) as needed.

PLEASE IDENTIFY:
PAGE ____ OF _____

BRAND FAMILY INFORMATION

Brand Family: _____ ☐ Cigarette ☐ RYO

CURRENT MANUFACTURER *(Check appropriate box below.)*

☐ The certifying manuafcturer actually manufacturers the brand family identified above.

☐ A different manufacturer, other than the certifying manufacturer, actually manufacturers the brand family identified above. *Attach a copy of all contract manufacturing agreements between the certifying manufacturer and the actual manufacturer for the brand family identified above.*

OTHER MANUFACTURERS *(Check appropriate box below.)*

☐ Provide the name and address of any manufacturer(s), other than the certifying manufacturer, who actually manufacturered the brand family identified above at any time between January 1, 2009, and the current date.

Name: _____

Address: _____

☐ Not applicable.

TRADEMARK INFORMATION *(Check appropriate box below.)*

☐ Manufacturer owns a United States Registered Trademark for the brand family identified above.

Trademark serial or registration number: _____

☐ Manufacturer does not own a United States Registered Trademark for the brand family identified above. *Attach any written contracts or agreements indicating the authority to manufacture the brands, or written authorization from the trademark holder.*

Trademark serial or registration number: _____

☐ A United States Registered Trademark does not exist for the brand family identified above.

BRAND FAMILIES TO BE REMOVED

List all cigarette and roll-your-own ("RYO") tobacco brand families currently on the Kansas Directory of Compliant Participating Manufacturers that you request to be removed.

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

ACKNOWLEDGEMENT OF ADDITIONAL REQUIREMENTS

☐ Manufacturer acknowledges that it is responsible for complying with all federal and state regulations, including the Federal Family Smoking Prevention and Tobacco Control Act.

☐ Manufacturer acknowledges that any cigarettes in this certification that are not also certified under the Fire Safety Standards and Firefighter Protection act (K.S.A. 31-601 *et seq.*) are not legal for sale in Kansas.

SUPPLEMENTAL DOCUMENTATION

The following attachments must be submitted with this certification form. If any requested attachments are not applicable, please mark "N/A." ***Failure to attach the documents in their entirety will result in an incomplete certification.***

ATTACHED	N/A	
☐	☐	**CDC Approval Letter.** Provide a copy of the *current* United States Center for Disease Control ("CDC") ingredient listing compliance letter(s) for each cigarette brand family. If a letter for this year's certification is not yet available, provide a copy of the written request addressed to the CDC. *Note: Failure to meet this requirement will result in an incomplete certification.*
☐	☐	**Contract Manufacturing Agreements.** Provide a copy of all contract manufacturing agreements for any brand family of cigarettes or RYO tobacco that is manufactured by an entity other than the certifying manufacturer.
☐	☐	**FTC Approval Letter.** Provide a copy of the *current* United States Federal Trade Commission ("FTC") approval letter(s) for health-warning rotation plan(s) for each of the cigarette brand families. If a letter for this year's certification is not yet available, provide a copy of the written request addressed to the FTC. *Note: Failure to meet this requirement will result in an incomplete certification.*
☐	☐	**Packaging Samples.** Provide a packaging sample for each cigarette or RYO tobacco brand family. Digital copies of packaging samples are preferred. If the packaging samples provided with last year's certification have not changed, you may disregard this requirement and check the box designated "N/A."
☐	☐	**TTB Permit.** Provide a copy of the manufacturer's or first importer's United States Alcohol and Tobacco Tax and Trade Bureau ("TTB") permit.

I certify that the above required documentation to be submitted with this certification is attached. I understand that failure to provide the required documentation will result in an incomplete certification.

_____

Signature of Authorized Officer or Agent

VERIFICATION OF CERTIFICATION

I certify that, to the best of my knowledge, all of the information contained in this certification and any attachments are true and accurate, and that I am authorized, under the laws of the state of Kansas or the jurisdiction where the manufacturer resides or is organized, to bind the manufacturer making this certification.

I certify that by including a brand family in this certification, manufacturer affirms that the brand family is deemed to be its cigarettes for purposes of calculating its payments under the Master Settlement Agreement, including any brand families for which manufacturer does not own a United States Registered Trademark.

I certify under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct.

Executed this _____ day of _____, 20_____.

SUBMISSION OF PM CERTIFICATION FORM

Mail this completed form and all attachments to:

Office of the Kansas Attorney General
Attn: Tobacco Enforcement Unit
120 S.W. 10th Ave., 2nd Floor
Topeka, KS 66612-1597

_____
Signature of Authorized Officer or Agent

_____
Name *(Please Print)*

_____
Title *(Please Print)*