From:	Ibarra-Pratt, Ele
To:	Villa, Anthony
Subject:	FW: Cheyenne-Follow-Up
Date:	Thursday, April 13, 2017 9:02:22 AM
Attachments:	image001.png

From: Scheineson, Marc [mailto:Marc.Scheineson@alston.com]
Sent: Thursday, April 13, 2017 9:01 AM
To: Ibarra-Pratt, Ele
Subject: RE: Cheyenne-Follow-Up

Thanks, Ele. Appreciate your follow-up and continued communication.
Some understanding of the agenda, or the scope of the discussion (other than discussion of the Warning Letter and our response), would also be helpful to insure that we are prepared and that the meeting is productive. Best, Marc.

From: Ibarra-Pratt, Ele [mailto:Elenita.IbarraPratt@fda.hhs.gov]
Sent: Wednesday, April 12, 2017 7:59 PM
To: Scheineson, Marc <Marc.Scheineson@alston.com>
Subject: RE: Cheyenne-Follow-Up

Marc,

I am still trying to coordinate internally and will try to confirm with you on the date and time by the end of this week. Thank you in advance for your understanding.

Regards,
Ele

Office of Compliance and Enforcement
FDA Center for Tobacco Products
Elenita.Ibarrapratt@FDA.hhs.gov | 301.796.9235
www.FDA.gov/Tobacco | @FDATobacco

CENTER FOR TOBACCO PRODUCTS

From: Scheineson, Marc [mailto:Marc.Scheineson@alston.com]
Sent: Wednesday, April 12, 2017 2:34 PM
To: Ibarra-Pratt, Ele
Subject: RE: Cheyenne-Follow-Up

Ele, please confirm that you received this email and that a meeting the afternoon on May th th

10 works at your end. The alternative is the morning of Friday, May 12 , whichever is most convenient. Best, Marc.

From: Scheineson, Marc
Sent: Tuesday, April 11, 2017 4:00 PM
To: 'Ibarra-Pratt, Ele' <Elenita.IbarraPratt@fda.hhs.gov>
Subject: Cheyenne-Follow-Up

Ele, per our discussion, the best date/time for Cheyenne to meet with FDA-CTP would be the afternoon of May 10th (around 2 p.m. or so) if convenient. Ralph Brown of Cheyenne is planning to attend the TMA meeting (evening of the 10th and 11th) and is scheduled to arrive in DC at 11:20 a.m. on the 10th. Once a meeting date/time is confirmed, we can send you a list of participants, and ask the same from CTP. Thanks for your follow-up. Best, Marc.

Marc J. Scheineson, Esq.
Alston & Bird LLP
950 F Street, N.W.
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(202) 239-3465 (Office)
(202) 344-5848 (Mobile)
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marc.scheineson@alston.com

From:	Ibarra-Pratt, Ele
To:	Kabaria, Swati; Villa, Anthony; Marshall, Byron; Hills, Bryan
Subject:	Fwd: Cheyenne- Filtered Cigar Proposal.DOCX
Date:	Tuesday, June 20, 2017 6:12:16 PM
Attachments:	Cheyenne FOIA Letter - May 23 2017 .pdf Cheyenne- Filtered Cigar Proposal_1 (2).DOCX
Importance:	High

From: "Scheineson, Marc"
Sent: Tuesday, June 20, 2017 5:24 PM
To: "Simoneau, Ann"
CC: "Mednick, David" ,"Ibarra-Pratt, Ele" ,David Scott ,Ralph Brown ,"Carroll, Brendan"
Subject: Cheyenne- Filtered Cigar Proposal.DOCX

Attached for your review and consideration is Cheyenne's response to the May 10, 2017 meeting discussing the Warning Letter about its cherry flavored filtered cigars. Please contact my colleagues or me with any questions, of if we may be of further assistance. Best, Marc.

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Marc J. Scheineson Direct Dial: 202-239-3465 Email: marc.scheineson@alston.com

June 20, 2017

VIA EMAIL (ann.simoneau@fda.hhs.gov)

DPAL-WL Response, Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Cheyenne International LLC December 9, 2017 Warning Letter Re: Flavored Filtered Cigars

Dear Ann:

The purpose of this letter is twofold: 1) to confirm in writing the contents of the meeting between Cheyenne International, LLC (Cheyenne) and the Food and Drug Administration (FDA) Center of Tobacco Products (CTP) on May 10, 2017 to discuss the Warning Letter issued to Cheyenne on December 9, 2016, and Cheyenne's response that was submitted on December 30, 2016; and 2) to outline next steps that Cheyenne proposes to take to reach a mutual resolution with FDA-CTP.

Meeting Summary

On May 10, 2017, representatives from Cheyenne (Ralph Brown and David Scott) and its FDA regulatory counsel (Marc Scheineson and Brendan Carroll) met with individuals from CTP's Office of Compliance and Enforcement and the FDA Office of Chief Counsel to discuss the December 9, 2016 Warning Letter and Cheyenne's response. You led the meeting which lasted approximately 1-hour.

During this meeting, you indicated that FDA-CTP received and reviewed the response submitted by Cheyenne on December 30, 2016. You next explained that CTP requested this meeting in order to discuss the Warning Letter including evidence it had gathered to support FDA's position that Cheyenne filtered cigars are perceived by consumers as cigarettes, and to possibly discuss a mutual resolution.

As the officiating individual, you explained that it was the Agency's position that Cheyenne 100s Wild Cherry cigars meet the definition of cigarette based on the appearance of the package and labeling. This position is reportedly supported by copy testing and consumer perception stud(ies) in which the consumers perceived that the cigars were cigarettes. This research was conducted by FDA-CTP's Office of Science (OS). According to CTP, the conclusion of the study was that participating consumers examined a number of factors and determined that because of the product package size and label, the product was a cigarette and not a cigar.

Cheyenne stated that it could not respond to findings from a study it had not seen, but indicated, at your request, that the Company could request a complete copy of the study under the Freedom of Information Act (FOIA). We agreed to review/comment carefully on its findings once received. Cheyenne further requested that CTP help expedite a complete response to the FOIA request. Cheyenne also stated that revelation of an unseen CTP-OS study did not change its position as detailed in the detailed Warning Letter response.

At the end of the meeting, Cheyenne agreed to CTP's request that it submit a proposal to FDA outlining next steps that Cheyenne would take to resolve this matter. This brief proposal is set forth below.

Cheyenne Proposal

Cheyenne's proposal for each of the steps that the Company proposes to take to address the concern raised in FDA's Warning Letter includes the following:

- Cheyenne submitted a request under the Freedom of Information Act (FOIA) for the "Study that Supports the December 9, 2016 Warning Letter" that you referenced during the May 10, 2017 meeting

    - Status: Completed. This FOIA request was FAXed and delivered to the FDA FOIA Office on May 23, 2017 (see copy attached). We have not received any acknowledgement, or the 20-day determination letter required by 21 CFR §20.41(b).

- Once Cheyenne receives this study (including all the components summarized in the FOIA Request), it will immediately review its methodology, contents and ultimate conclusions, to understand the basis of CTP's position as articulated in the Warning Letter and during the May 10, 2017 meeting. Cheyenne will evaluate whether a supplemental response is appropriate based on the design and results of the study.

    - Status: Pending receipt of the Study per the FOIA request.

- Cheyenne, in consultation with other members of industry (including the three other tobacco manufacturers that received the Warning Letter dated December 9, 2016), will evaluate whether it is appropriate to commission their own study regarding consumer perception of similarly packaged cigar products. Any

additional study would be based on a protocol design reviewed and agreed to in advance by CTP.

  - Status: Pending receipt and analysis of CTP-OS Study, and industry discussion.

- Cheyenne submitted a Rotational Warning Plan pursuant to 21 CFR §1143.5 that is awaiting CTP review and comment. It is revising its own labeling to comply with the terms of the Deeming Rule (e.g., use of one of six rotating warnings 4 of which include prominent use of the word "cigar" that must consume at least 30% of each of the two principal display panels on each package).

- Cheyenne is reviewing and evaluating its current labels, labeling and packaging to assess whether any changes are appropriate (e.g., increasing the font size and prominence of the word "Cigar").

  - Status: Pending. Cheyenne has begun drafting new and modified artwork for all cigar products, including increasing the prominence of certain statements and inclusion of required health warning statements, in order to comply with the new requirements under the Final Deeming Rule (which have recently been delayed until August 10, 2017). Cheyenne will evaluate any such changes in accordance with CTP's response to its Rotational Warning Plan.

- Cheyenne seeks to maintain an open line of communication with FDA-CTP to help resolve these issues as new developments occur, including critique and discussion of the CTP-OS consumer perception study. We will notify FDA-CTP once this FOIA request has been fulfilled, and Cheyenne has reviewed the study.

Thank you again for the opportunity to discuss this issue on May 10, 2017. We hope that we can continue to work cooperatively toward a mutual resolution of this matter.

Please contact Brendan Carroll or me with any questions or if we may be of further assistance.

Marc J. Scheineson

enclosure
cc: David Mednick, Esq. (via email)
Ms. Ele Ibarra-Pratt (via email)

Mr. David Scott (via email)
Mr. Ralph Brown (via email)

From: Ibarra-Pratt, Ele
To: Gu, Michael; Marshall, Byron; Kabaria, Swati
Subject: FW: Revised Cheyenne- WL Response (Final).DOCX
Date: Friday, December 30, 2016 5:05:56 PM
Attachments: Cheyenne- WL Response (Final) 1 (6).DOCX
Importance: High

FYI

From: Scheineson, Marc [mailto:Marc.Scheineson@alston.com]
Sent: Friday, December 30, 2016 5:05 PM
To: Simoneau, Ann; Ibarra-Pratt, Ele; CTP Office of Compliance
Subject: Revised Cheyenne- WL Response (Final).DOCX
Importance: High

Please substitute this letter for the letter sent previously which replaces a small typo in the previous letter. Sorry for any confusion (but it is Friday afternoon before the New Year). Best, Marc.

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December 30, 2016

OVERNIGHT MAIL

DPAL-WL Response
Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Cheyenne International, LLC Warning Letter Response
(RW 1600609)

Dear Ms. Simoneau:

Attached for your review and discussion is a response by Cheyenne International LLC (Cheyenne) to the Warning Letter dated and received by Cheyenne on December 9, 2016 (RW 1600609). The Warning Letter references your review of Cheyenne's website at http://www.cheyennecigars.com. It alleges that Cheyenne's Wild Cherry 100's Cigars labeled as cigars meet the definition of "cigarettes" under §900(3) of the Federal Food, Drug and Cosmetic Act (FDCA). Allegedly, as cigarettes, and not filtered cigars, a natural or artificial characterizing flavor is prohibited, thereby rendering this product adulterated and misbranded under the FDCA.

Cheyenne is a small tobacco product manufacturer (STPM); one of the few domestic tobacco product manufacturers remaining in the United States. We created hundreds of well-paying full-time jobs in rural Grover, NC with health and retirement benefits. Regulatory compliance has been and remains a top priority of Cheyenne. We were among the first in the industry to limit youth access to on-line promotion, limit that promotion, and to include prominent disclaimers concerning underage use and health risks on all our packaging and labeling. These steps were taken long before FDA obtained regulatory jurisdiction over tobacco products.

Since the inception of the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009, to which we actively assisted in drafting the STPM-related provisions, we have continued to place a strong emphasis on compliance with the TCA. We have been, and remain, cooperative and fully compliant with all FDA laws, regulations and procedures. However, we are greatly troubled by the alleged "flavored cigarette violation," which we

believe represents a gross misinterpretation and mischaracterization by FDA of Cheyenne Wild Cherry 100's Cigars as cigarettes. For the many reasons outlined below, and discussed in greater detail in our attached response, we object to the premise and allegations made in FDA's Warning Letter and the attendant press associated with its release. These reasons include:

- Policy Issue Not Compliance Issue. FDA-CTP is using its compliance and enforcement powers, in the form of a Warning Letter, improperly to try to enact policy to ban flavored filtered cigars and restrict consumer choice for alternatives to cigarettes, rather than using its rulemaking authorities through promulgation of performance standards, including public input, as envisioned in the TCA.

- No Evidence to Support Consumer Confusion. Existing evidence is contrary to FDA's assumption that underage use of flavored filtered cigars has increased, or that consumers believe that Cheyenne Wild Cherry 100's filtered cigars are actually cigarettes because of the size, shape or packaging of these products. No such evidence is cited, or included in the Warning Letter, as justification for CTP's conclusion that "FDA has determined that you sell or distribute flavored cigarette products, such as Cheyenne 100s Wild Cherry." Basic common sense would indicate that if flavored filtered cigars were offered, or likely to be purchased by consumers as cigarettes, sales of these cigar products would constitute substantially in excess of 1-2% compared to total cigarette sales since they offer flavorings banned in cigarettes and cost about 1/3 the cost of cigarettes due to lower federal and state excise taxes.

- No Conversion of Flavored Cigarettes to Flavored Cigars. Cheyenne never manufactured or sold flavored cigarettes at any time before or after enactment of the TCA. Flavored filtered cigars, which include flavors like cherry, have been sold as cigar products for over 100 years. Cheyenne has made and marketed these products since 2004. The TCA, enacted in 2009, could have banned these products, as it did cigarettes, if that was the legislative intent of Congress, which it was not.

- Same Definition Interpreted Differently by Treasury/FTC. FDA is ignoring the historic and consistent interpretations of the identical definition by other more experienced government tobacco regulators. The definition of "cigarette" contained in §900(3) FDCA referenced in the Warning Letter was drawn verbatim from the Internal Revenue Code (enforced by the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) which assesses federal excise taxes) and from the Federal Cigarette Labeling and Advertising Act (enforced by the Federal Trade Commission).

- Government Certification as Cigars. TTB, for example, tested and certified Cheyenne flavored filtered cigar products as cigars, eligible for lower federal excise taxes, based on a federal government Revenue Ruling consistently applying this identical definition. As part of TTB's analysis, the Cheyenne brown tobacco wrappers were tested and certified to contain at least 2/3 tobacco. The filler was tested and certified to be composed of traditionally harsher air-cured low sugar burley

tobacco blends used in cigars which were not intended to be inhaled (v. high sugar flue-cured oriental tobacco blends used in cigarettes which were intended to be inhaled). The package labels were carefully reviewed and certified by TTB to contain conspicuous cigar descriptors with sufficient prominence to eliminate any confusion for reasonable consumers, who were determined, therefore, to be unlikely to purchase the products believing them to be cigarettes and not cigars.

- Elimination of Small Business. As FDA may realize, all these statutes using the same definitions work together. Therefore, if filtered cigars are determined to be cigarettes under this established definition, it would create a government "feeding frenzy." States would require the use of low ignition propensity paper required of all "cigarettes," thereby eliminating this product category entirely. The federal government and each state attorney general would file criminal tax evasion lawsuits and seek billions of dollars in unpaid cigarette excise taxes. The USDA would seek unpaid "buy out" payments, and the entire structure of the TCA user fees and Tobacco Master Settlement Agreement would be recast to increase Cheyenne payments to the point that the Company could be thrust into bankruptcy with the resulting loss of all rural Grover, NC jobs and those of primary suppliers and vendors. Any public health benefit would be *de minimis* because of the relatively low volume of filtered cigar sales. Consumers would lose another non-inhaled product in the interest of inhaled chain-smoked sweet cigarette alternatives.

Despite the clear legal authority for Cheyenne to continue to market and sell flavored filtered cigars, including Wild Cherry 100's, in the interest of mutual cooperation and respect, Cheyenne agrees to address the concern expressed in the FDA-CTP Warning Letter by continuing specific actions summarized in Section B. 1-6 of the response attached.

This letter also authorizes FDA to communicate directly with our regulatory counsel, Marc J. Scheineson, Esq., at Alston & Bird, 950 F Street, N.W. Washington, D.C. 20004; 202-239-3465; marc.scheineson@alston.com, with respect to any issues related to this matter, or any other issues with respect to Cheyenne. Please contact Alston & Bird if you have questions or wish to discuss this matter further.

Thank you for your review and consideration of this response.

Respectfully submitted,

David A. Scott
Chief Executive Officer

enclosures
cc: Ms. Ele Ibarra-Pratt (via email)
Marc J. Scheineson, Esq. (via email)
Mr. Ralph Brown (via email)

Response

A. Background

Cheyenne is a small tobacco product manufacturer (STPM) as defined under §900(16) of the FDCA. Its manufacturing operations remain in the U.S., in Grover, NC. Cheyenne restored domestic product manufacturing to this depressed rural region and reemployed hundreds of Americans with well-paying, full-time manufacturing jobs that include full health and employer-funded retirement benefits. It produces a full-line of tobacco products including machine-made filtered cigars and cigarillos. These cigar products all contain traditional air-cured low-sugar content burley tobacco filler blends and brown homogenized tobacco leaf wrappers. Many of these cigar products contain flavorings selected exclusively to meet the expressed preferences of adult smokers to whom Cheyenne has sold these tobacco products since 2004; at least 5-years prior to the enactment of the TCA.

As a small business focused on regulatory compliance, Cheyenne has remained fully compliant with all FDA regulations, procedures and guidance stemming from the TCA, despite the fact that many of the small business exemptions and/or transition rules required by the TCA, and specifically negotiated by Cheyenne and other small businesses, have been ignored or "reinterpreted" during implementation of the TCA.

In 2009-10, Cheyenne, and its FDA regulatory counsel, took an active role explaining existing interpretations of the legal distinction between filtered cigarettes and filtered cigars to the new CTP Director, Dr. Lawrence Deyton. This dialogue occurred in response to initial attempts by FDA, and deputized state health officials, soon after enactment of the TCA, to seize flavored little cigars in addition to flavored cigarettes based on a misinterpretation of the cigarette flavor ban. Dr. Deyton and CTP agreed to refrain from such action based on these discussions, review of this analysis, and withdrawal of a legal complaint filed by another manufacturer, Kretek International, Inc.

Cheyenne also responded to requests for comments by FDA regarding this very issue as part of the Proposed Rule, "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products Required Warning Statements of Tobacco Products" (April 25, 2014) (the "Proposed Deeming Rule"). Specifically, as part of this Proposed Deeming Rule, FDA requested comments regarding "the characteristics or factors it should consider in determining whether a particular tobacco product is a 'cigarette' as defined in section 900(3) of the FD&C Act and, consequently, subject to the prohibition against characterizing flavors, despite being labeled as a little cigar or other non-cigarette tobacco product."[1]

[1] 79 Fed. Reg. 23142, 23144 (April 25, 2014).

In response to comments received on the Proposed Deeming Rule including this specific request for information, and perhaps based on opposition by the Office of Management and Budget, FDA declined in the final rule to establish any "characteristics or factors" and instead declared its intention – in the future – to address this issue by issuance of a proposed product standard:

> FDA is not banning flavored tobacco products with this final deeming rule. To address concerns with the growing flavored cigar market and its impact on youth and young adult initiation with tobacco products, FDA is announcing here that it intends to issue in the future a proposed product standard that would prohibit characterizing flavors in all cigars, including cigarillos and little cigars.[2]

Despite a number of well-intentioned, but completely incorrect and unsubstantiated, comments from the public health community that smaller sized cigars are being marketed and used as cigarettes and, therefore, that FDA should communicate that such products are subject to the cigarette flavor ban, FDA instead responded that it "underst[ood] and appreciate[d] comments regarding the role that flavored little cigars, or similar products, might play on initiation of tobacco product use and dual use," but ultimately stated that FDA "will continue to determine whether a product is a 'cigarette' under the FD&C Act and subject to the statutory flavor ban on a case-by-case basis."

The issuance of this Warning Letter appears to represent such a "case-by-case" determination whereby the Agency has made the determination that Cheyenne Wild Cherry 100's Cigars are "cigarettes" under the FDCA. We note that FDA stated in the Warning Letter that the Agency had "recently reviewed the website http://www.cheyennecigars. com" in order to make the determination that these products meet the definition of the FDCA's definition of a "cigarette," but otherwise provided no specifics concerning what content or material it found to support this determination. We are accustomed to viewing Warning Letters related to alleged advertising and promotion violations issued by other FDA product centers, and reviewed by the Office of Chief Counsel, that specifically repeat the promotional language determined by FDA to constitute "adulteration," and "misbranding." No such language from Cheyenne's website was included in the CTP Warning Letter.

[2] 81 Fed. Reg. 28974, 29055 (May 10, 2016).

Before responding to the specific violation alleged in this Warning Letter below, as the Agency knows, "[t]he requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its results . . . ." *Public Citizen v. FAA*, 988 F.2d. 186, 197 (D.C. Cir. 1993). It is a general and straightforward principle of administrative law that "the agency must explain why it decided to act as it did." *See Butte County California v. Hogen*, No. 1:08-cv-5179 (D.D.C. July 13, 2010) (asserting that "[t]he agency's statement must be one of 'reasoning'; it must not be just a 'conclusion'; it must 'articulate a satisfactory' explanation' for its action."). No agency can adopt an *ipse dixit* approach to making a determination. *See D&F Afonso Realty Trust v. Garvey*, 216 F.3d 1191, 1196 (D.C. Cir. 2000) (concluding that the agency did not consider relevant factors or sufficiently explain the basis of its hazard determination).

Cheyenne, likewise, did not receive sufficient explanation, and, therefore, does not understand the relevant factors that FDA reviewed on Cheyenne's website to support the conclusion that "FDA has determined that you sell or distribute flavored cigarette products, such as Cheyenne 100's Wild Cherry" (Warning Letter, pg. 1, 6th paragraph, "Flavored Cigarette Violation").

Nonetheless, we respond in full to these allegations below:

B. Warning Letter Violations

The basis of this Warning Letter is that FDA determined that Cheyenne Wild Cherry 100's Cigars are, in fact, cigarettes. We respectfully, but strongly disagree for the reasons stated in detail below. However, in the interest of mutual cooperation and respect, we agree to continue to take the following steps in order to remove any doubt concerning the correct regulatory status of this product and other Cheyenne flavored filtered cigars:

1. Cheyenne will use the descriptor "cigar" conspicuously and prominently wherever the brand name appears on all advertising and promotional materials including on-line and printed materials.

2. We will never use tobacco filler other than pure air-cured low-sugar cigar blends and never use any Oriental tobacco in any of our flavored filtered and other cigar products.

3. We agree never to market, sell or use any product names, descriptors, flavors or advertising targeting under-age smokers.

4. Cheyenne shut down all blogs, chat-rooms and other forms of company-sponsored on-line communications from customers, vendors, or others, which could include information confusing to consumers or regulators concerning the identity of its flavored filtered cigar products.

5. We will continue to monitor social media regularly for any misinformation that could confuse consumers concerning the classification and identity of our flavored filtered cigar products and cigarette products as recommended in Agency guidance concerning use of social media (currently applicable to drugs, biologics and devices)[3].

6. We intend to maintain open communications with FDA in the hope that any information that FDA-CTP finds objectionable concerning our flavored filtered cigars will be discussed and withdrawn as appropriate.

Response to Warning Letter Allegations

Based on this mischaracterization of an entire product category, FDA cited adulteration and misbranding violations under §§902(5) and 903(a)(1), as well as a flavored cigarette violation under §907(a)(1) FDCA. For the reasons explained below, all of these alleged violations are inappropriate as applied to Cheyenne's Wild Cherry 100's filtered cigars:

1. The definitions of "cigarette," "cigar" and "little cigar" under the FDCA, FCLAA and IRC clearly define the characteristics of these different types of products.

   a. Cigarette

The term "cigarette" is defined under §900(3) of the FDCA as a product that:

(i) is a tobacco product; and

(ii) meets the definition of the term 'cigarette' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

The term "cigarette" as defined in §1332(1) of Chapter 36 of the Federal Cigarette Labeling and Advertising Act of 1966 (FCLAA) (incorporated by reference into §900(3) of the FDCA) means:

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

(B) any roll of tobacco wrapped in any substance containing tobacco, which, because of its appearance, the type of tobacco used in the filler, or its

[3] *See* Guidance for Industry, Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014).

> packaging and labeling, is likely to be offered, or purchased by, consumers as a cigarette described in subparagraph (A).

The definition of "cigarette" in the FDCA mirrors the definition of "cigarette" contained in the Internal Revenue Code (IRC) administered by the Department of the Treasury,[4] and the FCLAA administered by the Federal Trade Commission from which the identical TCA definition was drawn.

b. Little Cigar

The term "little cigar" is defined under §900(11) of the FDCA as a product that:

> (A) is a tobacco product; and
>
> (B) meets the definition of the term 'little cigar' in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

The term "little cigar" as defined in §1332(7) of Chapter 36 of the FCLAA) (incorporated by reference into §900(3) of the FDCA means "any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1)) and as to which one thousand units weigh not more than three pounds."

c. Cigar

The term "cigar" is defined under the Final Deeming Rule (incorporated into 21 C.F.R. §1143.1) is a tobacco product that:

> (i) is not a cigarette; and
>
> (ii) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

In conjunction with these statutory definitions, the Alcohol, Tax and Trade Bureau of the Department of the Treasury (TTB) issued detailed regulations and Revenue Rulings distinguishing between cigarettes and cigars for purposes of excise tax determinations. These classifications have been applied successfully since approximately 1954. TTB assesses "[a] combination of other factors [that] must also be considered" in determining whether a product is a cigar or a cigarette.[5] These distinctions between a cigarette and cigar depend upon a number of factors including the type of tobacco used in the filler, the type of wrapper, the weight of the product and the labeling of the product.

---

[4] *See* 15 U.S.C. §1332(1) and 26 U.S.C. §702.

[5] *See* ATF Ruling 73-22 and Procedures 73-5 and 76-2.

With a full understanding of the longstanding distinctions between cigarettes and cigars, and in order to create consistency between agency regulation, Congress carefully defined "cigarette" in the FDCA in exactly the same manner as it had before in the IRC and the FCLAA. The FDCA explicitly refers to cigars and little cigars as a separate classification of tobacco products than cigarettes. The definition incorporates the historic distinction between cigars and cigarettes that has been included in prior Congressional legislation and administrative regulations. In fact, the term "little cigar" was initially defined in §900(11) of the FDCA (through incorporation of the definition in the FCLAA) as "any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning ["cigarette" under the FCLAA] and as to which one thousand units weigh not more than 3 pounds." The statutory definitions of cigar and cigarette are, therefore, mutually exclusive of one another. Later, as discussed above, FDA defined "cigar" in the Final Deeming Rule (incorporated into 21 C.F.R. §1143.1), which also maintains a regulatory definition that is mutually exclusive of the term "cigarette."

The rationale behind the statutory differences between "cigarette" and "cigar" or "little cigar" stem from a long list of differences between the characteristics of the two products as well as demographic and user patterns. This classification is also based on statutory construction, rulemaking, judicial precedent, research by government experts, and by consumer practices and behavior.

First, cigars contain filler composed largely of harsher air-cured, low-sugar tobacco blends including burley tobacco, whereas cigarettes contain filler composed of sweeter flue-cured blends including Oriental tobaccos. In fact, ATF Ruling 73-22 explicitly stated that "[t]he inclusion of flue-cured or aromatic (Oriental) tobaccos—which traditionally have been the primary constituents of cigarette filler—can contribute significantly to making a product cigarette-like."

Second, cigars use wrappers that are made from natural brown leaf tobacco or reconstituted tobacco (consisting of at least 2/3 leaf tobacco by weight), as required by TTB). Cigarettes are wrapped in white paper which is required currently to consist of ventilated fire-safe paper with designated extinguishing qualities (e.g., starch bands or gaps). This is another important distinction in preserving the tobacco character (e.g., taste, aroma, identifiable chemical components).

Third, the product labeling of cigars differs from cigarettes. These smaller sized cigars are conspicuously and unmistakably labeled as "LITTLE CIGARS," "SMALL CIGARS" or "CIGARS," as required by TTB.[6] A conspicuous "cigar" declaration must appear on the front, back and bottom panels of such products.[7] The terms, "CIGARS," "SMALL CIGARS" and "LITTLE CIGARS" are specifically required to appear in direct

[6] *See* 27 CFR §40.214.

[7] *See* ATF Ruling 73-22.

conjunction with, parallel to, and in substantially the same conspicuousness of type and background as, the brand name each time the brand name appears, which is true for all small-sized cigars, including those sold in packs of 20.[8]

Cheyenne Wild Cherry 100s Cigars unmistakably meet these very basic, but very important, requirements for appropriate classification as cigars. In fact, Cheyenne took the extra step of presenting these products to TTB for review and testing. TTB certified these products as cigars and not cigarettes in writing, including specifically Wild Cherry 100's (*see* TTB Certification as Exhibit 1). In summary, first, Cheyenne Wild Cherry 100's Cigars contain filler composed largely of harsher air-cured, low-sugar tobacco blends. Second, the cigar wrappers are dark brown because they are composed of reconstituted tobacco (consisting of at least 2/3 leaf tobacco by weight) – and not white fire-safe low ignition propensity paper. Third, in the product labeling (attached as Exhibit 2), numerous conspicuous "cigar" declarations appear prominently at the very top with the same conspicuousness of type as the brand name on the front, back and bottom panels of the label.

Smaller sized cigars, as defined by the law and subject to periodic review and examination by TTB, have been marketed since the early 1970s in their filtered form. Cheyenne has marketed and sold these products since it opened its business in 2004. It has never made or sold flavored cigarettes. As of 2007, Cheyenne marketed three types of Wild Cherry filtered cigars Contrary to well-intentioned, but legally incorrect and unsubstantiated, statements made by the public health community, the marketing and sale of these cigars is <u>not</u> a recent development that arose as a method to circumvent TCA cigarette flavor bans. It did <u>not</u> arise out of the more stringent regulation of cigarettes. The presence of flavored cigars in the marketplace is supported by a century of legislative history dating first to the Revenue Act of 1909 and continuing through the 1954 Internal Revenue Code, the Excise Reduction Act of 1965 and the 1973 Little Cigar Act. Filtered and flavored small cigars have held a lawful place on the U.S. market throughout this history. They have, likewise, maintained a consumer base, albeit a small consumer base with gross sales amounting to approximately 1-2% in comparison to total cigarette sales throughout this time (*see* for example, TTB 2015 Statistical Report, Exhibit 3).

2. <u>Cheyenne Wild Cherry 100's Cigars are not likely to be offered to, or purchased by, consumers as cigarettes</u>.

The definition of "cigarette" contained in §900(3)(B) provides FDA with the authority to treat a cigar product as a cigarette, and thereby ban characterizing flavors, if "it is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco" based on its appearance, filler, or packaging and labeling. Any smoker will attest that there is really no way to confuse a product containing harsher air-cured burley tobacco surrounded by a unventilated brown tobacco wrapper with a sweeter flue-cured Oriental tobacco cigarette surrounded by a white low ignition propensity paper wrapper. This is

[8] *See id*.

especially true for Cheyenne Wild Cherry 100's Cigars. Cigars, even if filtered and included in packs of 20, like the subject of this Warning Letter, burn differently, taste different, contain a different harder draw, have a different feel of the smoke in the throat, and are not ventilated. They are harsher tasting, even with flavoring, have a heavier more robust smell, and burn longer and hotter based on no ventilation in the tobacco wrapper or tipping paper.

We understand that in 2012, FDA issued a Request for Proposal (RFP) and contracted a polling firm to document, in part, whether consumers purchased filtered cigars believing them to be cigarettes.[9] According to this RFP, the primary objective of this contract was to "conduct a study to assess if flavored little cigars, because of their appearance or type of tobacco used in the filler, are likely to be depicted as and consumed by tobacco users as a cigarette." The results of that survey (e.g., research papers, if completed), to our knowledge, have never been made public, or at least not published or disseminated publicly by FDA.

In fact, we were able to examine the results of this study, provided as part of a May 2016 presentation, available at researchgate.net[10]. The statistical comparisons posted in PowerPoint by Battelle, awarded the contract by FDA, actually showed the contrary. Again, although unpublished, these results suggest that dual-user subjects had very different perceptions of the cigars versus their own-brand of cigarettes, which undermines any assertion that users where unaware of which was a cigarette and which was a filtered cigar, or that these products are substitutable. The results regarding subjective effects (e.g., "liking" a product) clearly demonstrated a significant difference and preference to cigarettes (6.0 percent of respondents) as opposed to cigars (3.0 of respondents). Such results are consistent with sales trends that demonstrate that cigarette sales outpace sales of small cigars by approximately 300 to one, and that U.S. sales of cigar products are declining (TTB 2015 Statistical Report, Exhibit 3).

Cheyenne's own internal sales data, as well as sales data of filtered cigars across the industry, supports the conclusion that no consumer confusion exists. Based on 2015 sales data, for example, in 2015, nearly 300 times more cigarettes were sold than the sale of small types of cigars (approximately 300 billion cigarettes compared to 1 billion small cigars and 6 billion large cigars). *See* http://www.ttb.gov/statistics/13tobstats.shtml, or Exhibit 3. If a filtered cigar was "likely to be offered to, or purchased by, consumers as

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[9] *See* "Experiment Study on the Subjective, Physiological and Puff Topography Measures of Little Cigars" (Solication Number: SSNDecember112011), available at https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=7aa8f1a270911a2609f6300eb8895833&_cview=1, which was subsequently awarded to Battelle Memorial Institute on September 21, 2012.

[10] *See* "Laboratory Smoking of Flavored and Unflavored Little Cigars and Cigarettes, Use Behavior, Toxicant Exposure, Subjective Effects and Risk Perceptions, *available at* https://www.researchgate net/publication/303382674_Laboratory_Smoking_of_Flavored_and_Unflavored_Little_Cigars_and_Cigarettes_Use_Behavior_Toxicant_Exposure_Subjective_Effects_and_Risk_Perceptions (attached as Exhibit 4).

a cigarette" because of its appearance, filler, or packaging and labeling, why were 300 times more cigarettes sold than small cigars in the U.S. in 2015 alone? This is especially perplexing because heavier filtered cigars are taxed significantly less and are, therefore, cheaper per pack depending on the state (e.g., $2 v. $6-$10 per pack). Filtered cigars can also be flavored while cigarettes are limited to tobacco and menthol flavors. The answer is obvious to smokers and industry experts, and has been verified by the unpublished research FDA commissioned. Cigars are not substitutable for cigarettes and consumers can clearly tell the difference between the two products. They have different tastes, ingredients, design, smoking characteristics and consumer demographics, such that they cannot be commonly mistaken by consumers for cigarettes. That is why TTB taxes Cheyenne's Wild Cherry 100's as cigars, and why they are treated as cigars by FTC under the FCLAA.

In addition to the differences in physical characteristics and labeling between cigars and cigarettes, there exist other notable differences with respect to the use of these products. Whereas cigarettes may be very addictive, are commonly inhaled and are chain-smoked by the pack, filtered cigars may be less addictive, are generally not inhaled, and are smoked in significantly lower numbers.[11]

C. Conclusion

In light of the above longstanding differences between cigarettes and cigars with respect to federal statutory definitions, product characteristics and usage, FDA mischaracterizes Cheyenne's Wild Cherry 100's Cigars as cigarettes. Identical definitions of cigarettes were adopted by Congress in tobacco-related legislation enacted prior to the TCA. The TCA used these familiar definitions to retain consistency between the definitions currently administered by TTB, USDA and FTC under various statutes and regulations. Cheyenne, therefore, rejects any allegation that its filtered flavored cigar products are adulterated and misbranded under §§902(5) and 903(a)(1), or constitute a flavored cigarette in violation under §907(a)(1) of the FDCA.

The Final Deeming Rule did not permit cigars to be re-classified as cigarettes under the FDCA (without establishing formal product standards using notice and comment rulemaking). FDA cannot, through selective enforcement or interpretation, seek action not authorized by statute or regulation. Although the Final Deeming Rule permits FDA to make determinations on a case-by-case basis, FDA provided no underlying factual support or released no evidence to prove that Cheyenne Wild Cherry 100's Cigars meet the definition of a cigarette, as interpreted previously and consistently by FDA, TTB, USDA and FTC, other than to repeat the language of the definition.

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[11] National Cancer Institute-Monograph 9- Cigars: Health Effects and Trends, pg. 40. *See* http://cancercontrol.cancer.gov/BRP/tcrb/monographs/9/index.html.

As the Agency is aware, and as Cheyenne demonstrated in this response, there exist long-recognized and unambiguous definitions of "cigar" and "little cigar." These definitions have evolved from the IRC, FCLAA, in the regulations and Revenue Rulings of TTB, and most recently in the FDCA. Throughout enactment and implementation of these, and other statutory, regulatory and interpretative provisions, the distinction between cigars and cigarettes has been consistent, well-established and well-vetted by lawmakers, regulators, consumer groups and industry alike. It is important that these definitions (for cigarettes, cigars, and little cigars) be respected uniformly, and consistently applied across the Federal Government by agencies authorized to administer the various laws that oversee this product regulation.

If FDA seeks to discuss this matter further, please contact our regulatory counsel, Marc Scheineson, at (202) 239-3465 (marc.scheineson@alston.com). If you disagree with the analysis prepared above, please explain why and permit us to meet to discuss this matter directly. Please also provide us with any valid scientific studies, or other information, that support FDA's position and the enforcement action you have taken.

Exhibit 1

Exhibit 1

DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, DC 20226

August 11, 2004

844000:LWC
5200

Mr. David A. Scott
Chief Financial Officer
Cheyenne International, LLC
701 S. Battleground Avenue
Grover, N.C. 28073

Dear Mr. Scott:

This is in response to your request of May 13, 2004, for an advance ruling on the tax status of two product lines that you wish to market as little cigars. The two product lines are (1) 'Derringer Little Cigar', which includes 9 styles and (2) 'Cheyenne Little Cigar', which includes 4 styles.

You submitted your request, with 25 sticks of each style enclosed in separately labeled plastic bags, sample graphics for the package and carton for each product line, and a sample of the wrapper material, to the Scientific Services Division (Laboratory) of the Alcohol and Tobacco Tax and Trade Bureau (TTB) in Beltsville, Maryland.

Our Laboratory has completed its examination of your samples, listed below:

T787	Derringer Full Flavor 100 Box
T788	Derringer Light Flavor 100 Box
T789	Derringer Menthol Flavor 100 Box
T790	Derringer Vanilla Flavor 100 Box
T791	Derringer Cherry Flavor 100 Box
T792	Derringer Full Flavor King Box
T793	Derringer Light Flavor King Box
T794	Derringer Menthol Flavor King Box
T795	Derringer Vanilla Flavor King Box
T796	Cheyenne Full Flavor 100 Box
T797	Cheyenne Light Flavor 100 Box
T798	Cheyenne Menthol Flavor 100 Box
T799	Cheyenne Wild Cherry Flavor 100 Box
T800	One-27mm Roll Schweitzer-Mauduit PAW-3 Wrapper

The Internal Revenue Code (IRC) at 26 U.S.C. 5702 (a), defines the term "cigar" as "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (b)(2))." Further, the IRC at 26 U.S.C. 5702 (b)(2) defines the term "cigarette" as "any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1)." The same definitions appear in the TTB regulations at 27 CFR 40.11.

Our Laboratory performed analyses on the Schweitzer-Mauduit wrapper material, and on the filler, wrapper, and physical features of each of the Derringer and Cheyenne samples. We find that:

(1) the Schweitzer-Mauduit wrapper material is consistent with reconstituted sheet tobacco,

(2) the filler tobacco of each of the samples is consistent with that of a cigar,

(3) the wrapper material of each of the samples contains nicotine, which is a primary indicator of tobacco, and

(4) each sample weighs less than three pounds per thousand, which is consistent with the standard that applies to little cigars for tax purposes under the IRC.

Further, the packaging that you intend to use for each of these products describes the products as "Little Cigars." Based on our Laboratory findings and the review of your product packaging, we find that these proposed products meet the standards for little cigars for purposes of the statutory and regulatory provisions administered by TTB.

Please be advised that we are evaluating the standards we use to make these assessments. We may publish new standards and laboratory procedures. While we do not expect to change the tax status of your products, we caution that such classifications are subject to review.

David A. Scott

If you have questions regarding this letter, please do not hesitate to contact Ms. Linda W. Chapman by telephone at 202-927-8181 or by e-mail at Linda.Chapman@ttb.gov or Ms. Amy J. Rogers by telephone at (202) 927-1606 or by e-mail at Amy.Rogers@ttbgov.

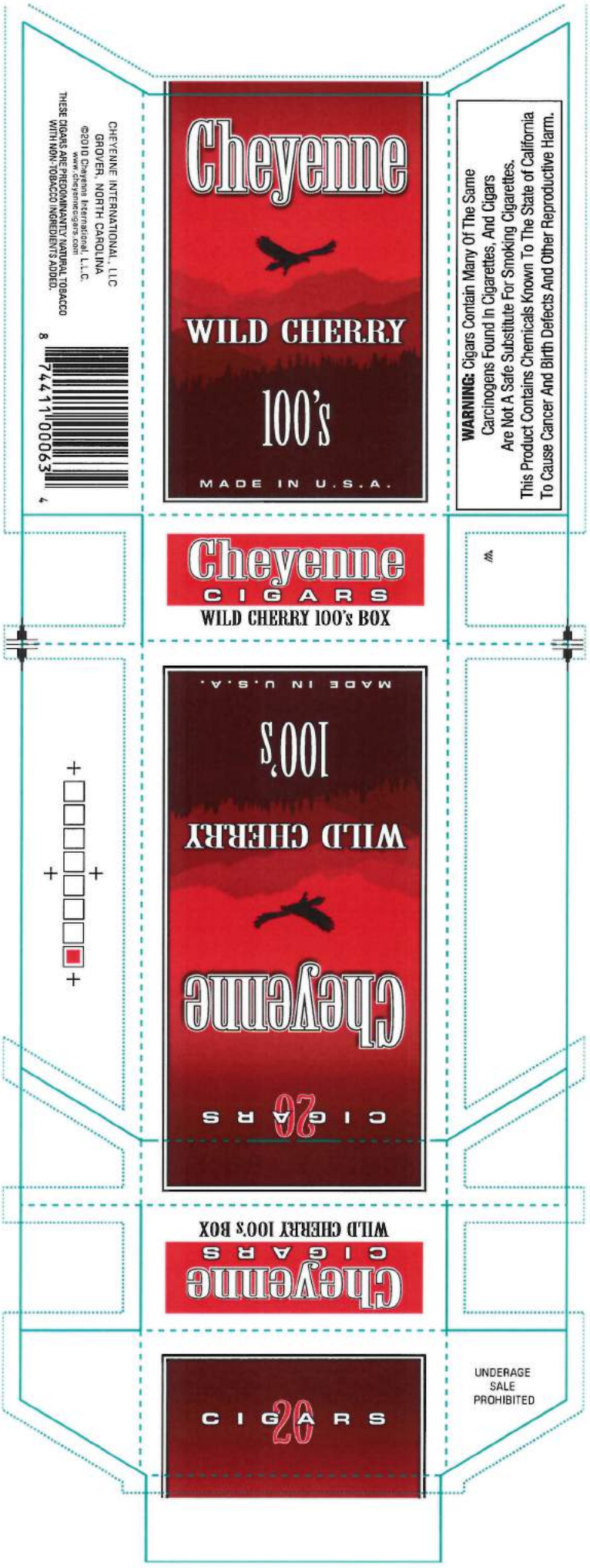
Sincerely,

William H. Foster
Chief, Regulations and Procedures Division

cc: Tobacco Unit, National Revenue Center
Chief Counsel
Director, Scientific Services Division

Exhibit 2

Exhibit 2


Cheyenne
WILD CHERRY
100's
MADE IN U.S.A.
CHEYENNE INTERNATIONAL, LLC
GROVER, NORTH CAROLINA
©2010 Cheyenne International, L.L.C.
www.cheyennecigars.com
THESE CIGARS ARE PREDOMINANTLY NATURAL TOBACCO WITH NON-TOBACCO INGREDIENTS ADDED.
8 74111 00063 4
WARNING: Cigars Contain Many Of The Same Carcinogens Found In Cigarettes, And Cigars Are Not A Safe Substitute For Smoking Cigarettes. This Product Contains Chemicals Known To The State of California To Cause Cancer And Birth Defects And Other Reproductive Harm.
Cheyenne
CIGARS
WILD CHERRY 100's BOX
MADE IN U.S.A.
100's
WILD CHERRY
Cheyenne
CIGARS
WILD CHERRY 100's BOX
Cheyenne
CIGARS
20
CIGARS
UNDERAGE SALE PROHIBITED

WARNING: Smoking Cigars Regularly Poses Risks Of Cancer Of The Mouth, Throat, Larynx, And Esophagus Similar To Smoking Cigarettes. This Product Contains Chemicals Known To The State of California To Cause Cancer And Birth Defects And Other Reproductive Harm.

Cheyenne
CIGARS
WILD CHERRY 100's BOX

UNDERAGE SALE PROHIBITED

8 74411 00070 2

Cheyenne
CIGARS
WILD CHERRY 100's BOX

THESE CIGARS ARE PROUDLY MADE WITH QUALITY NON-TOBACCO INGREDIENTS ADDED.

Exhibit 3

Exhibit 3

DEPARTMENT OF THE TREASURY

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

STATISTICAL REPORT - TOBACCO

Report Date: 07-JUL-2016

Report Symbol: TTB S 5210-12-2015

Reporting Period: December 2015

(Number of Cigarettes & Cigars - Pounds of Pipe, Chewing Tobacco, Roll-Your-Own & Snuff)

Manufactured Domestically or Received from Puerto Rico	Current Month	Prior Month	Prior Year Current Month	Current Year Cumulative Year to Date	Prior Year Cumulative Year to Date
Cigarettes - Small	17,551,336,935	22,432,939,875	16,427,139,981	283,810,261,179	277,581,659,973
Cigarettes - Large	0	0	0	0	0
Cigars - Small	58,833,063	73,143,365	49,906,483	827,268,539	1,071,672,816
Cigars - Large	444,516,794	453,894,765	536,786,233	5,956,028,700	7,190,918,623
Snuff	10,531,793	9,296,748	9,188,490	118,191,001	115,198,514
Chewing Tobacco	1,287,769	1,538,012	1,455,165	19,283,012	21,286,873
Pipe Tobacco	3,039,115	3,001,871	3,175,410	37,598,094	38,666,109
Roll-Your-Own Tobacco	232,019	244,036	170,947	3,451,255	3,190,000
Removed Taxable including from Puerto Rico					
Cigarettes - Small	20,126,083,101	19,261,263,382	17,891,348,973	259,294,293,391	254,509,382,303
Cigarettes - Large	0	0	0	0	0
Cigars - Small	40,417,300	45,009,139	43,773,152	530,680,751	542,454,495
Cigars - Large <= $763.222	401,373,131	417,325,140	545,060,406	5,260,785,434	6,704,507,094
> $763.222	126,173	106,555	216,507	1,852,986	4,947,195
Total Large	401,499,304	417,431,695	545,276,913	5,262,638,420	6,709,454,289
Snuff	10,564,141	9,256,170	9,249,692	116,987,888	113,664,849
Chewing Tobacco	1,536,137	1,555,263	1,736,622	19,352,433	21,335,199
Pipe Tobacco	3,058,260	2,543,515	3,129,799	36,189,864	37,784,963
Roll-Your-Own Tobacco	333,397	257,559	244,699	3,425,372	3,042,545
Removed Tax Exempt - Cigarettes					
Small - Export	1,373,721,280	1,346,138,400	2,468,626,800	20,819,483,620	20,382,508,200
Transfer to Export Warehouses	104,398,800	81,147,600	109,117,200	1,286,216,000	1,565,180,600
Use of the U.S.	11,016,000	600,000	5,352,000	40,816,000	33,899,200
Personal Consumption/Experimental	1,057,059	2,333,781	1,220,326	71,324,118	19,248,379
Total Small	1,490,193,139	1,430,219,781	2,584,316,326	22,217,839,738	22,000,836,379
Large	0	0	0	0	0
Removed Tax Exempt - Cigars					
Small - Export	24,566,200	46,584,000	17,169,200	289,123,715	530,201,775
Transfer to Export Warehouses	0	0	0	0	4,566,000
Use of the U.S.	0	0	0	0	0
Personal Consumption/Experimental	17,007	2,209	4,490	183,911	204,590
Total Small	24,583,207	46,586,209	17,173,690	289,307,626	534,972,365
Large - Export	2,352,980	8,627,000	14,480,480	150,537,585	222,961,965
Transfer to Export Warehouses	0	0	0	0	1,749,800
Use of the U.S.	0	0	0	0	0
Personal Consumption/Experimental	29,417	17,126	21,214	417,331	526,454
Total Large	2,382,397	8,644,126	14,501,694	150,954,916	225,238,219

NOTE: Changes in figures from prior reports could be due to amended reports being filed. This data is not final and may need to be amended.

	Current Month	Prior Month	Prior Year Current Month	Current Year Cumulative Year to Date	Prior Year Cumulative Year to Date
Removed Tax Exempt - Smokeless Tobacco					
Snuff - Export & To Export Warehouses	69,714	81,141	107,580	1,010,600	1,037,894
Other	786	653	1,966	14,123	18,692
Chewing Tobacco - Exp. & To Exp. Whs.	3,043	3,048	5,563	24,195	25,497
Other	164	112	73	2,962	3,431
Removed Tax Exempt - Pipe Tobacco					
Export and To Export Warehouses	175,870	105,094	67,910	1,186,809	675,160
Other	121	147	243	2,148	2,730
Removed Tax Exempt - Roll-Your-Own Tobacco					
Export and To Export Warehouses	66	4,008	0	36,436	27,994
Other	6	8	6	129	1,591
IMPORTED FROM FOREIGN COUNTRIES Entered/Withdrawn for Consumption (As reported by the Bureau of the Census in Publication IM 146)					
Cigarettes, Total (USTSA 2402.20.1000, 2402.20.8000, 2402.20.9000)	693,875,000	715,911,000	701,814,000	8,540,221,000	8,194,703,000
Cigars - Small (USTSA 2402.10.3030, 2402.10.8030)	1,684,000	2,993,000	958,000	23,505,000	21,403,000
Cigars - Large: (USTSA 2402.10.3070, 2402.10.6000)	355,505,000	520,479,000	456,045,000	6,251,663,000	5,967,001,000
(USTSA 2402.10.8050, 2402.10.8080)	33,483,000	29,845,000	19,132,000	230,183,000	202,556,000
Total Large	388,988,000	550,324,000	475,177,000	6,481,846,000	6,169,557,000
Snuff (USTSA 2403.99.2040)	28,402	64,811	43,036	583,932	702,966
Chewing Tobacco (USTSA 2403.99.2030)	43,682	71,968	52,380	858,688	630,212
Pipe Tobacco (USTSA 2403.10.2020, 2403.10.2080)	162,057	262,533	597,016	4,165,503	3,441,405
Roll-Your-Own Tobacco (USTSA 2403.10.2050)	15,245	17,747	6,195	239,432	194,950
Release to Domestic Factories Without Payment of Tax (Included also in above "Entered/Withdrawn for Consumption" Category)					
Cigarettes - Small	0	0	0	3,544,000	118,000
Cigarettes - Large	0	0	0	0	0
Cigars - Small	0	0	2	0	2
Cigars - Large	0	0	0	0	232,500
Snuff	0	0	0	16	45
Chewing Tobacco	0	0	0	0	0
Pipe Tobacco	0	132	0	18,732	0
Roll-Your-Own Tobacco	0	0	0	0	0
Onhand / Close of Business					
Cigarettes - Small	22,725,092,746	26,925,111,487	22,460,228,448		
Cigarettes - Large	0	0	0		
Cigars - Small	78,768,069	84,936,173	49,321,496		
Cigars - Large	418,832,065	472,214,687	527,555,995		
Snuff	3,302,582	3,401,394	3,262,463		
Chewing Tobacco	628,156	877,124	717,650		
Pipe Tobacco	1,844,632	2,022,279	2,142,607		
Roll-Your-Own Tobacco	255,319	353,417	139,733		

NOTE: Changes in figures from prior reports could be due to amended reports being filed. This data is not final and may need to be amended.

Exhibit 4

Laboratory Smoking of Flavored and Unflavored Little Cigars and Cigarettes; Use Behavior, Toxicant Exposure, Subjective...

Presentation · May 2016

DOI: 10.13140/RG.2.1.3130.7120

9 authors, including:

Bartosz Koszowski

Battelle Memorial Institute

47 PUBLICATIONS **175** CITATIONS

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Victoria H Coleman-Cowger

Battelle Memorial Institute

40 PUBLICATIONS **499** CITATIONS

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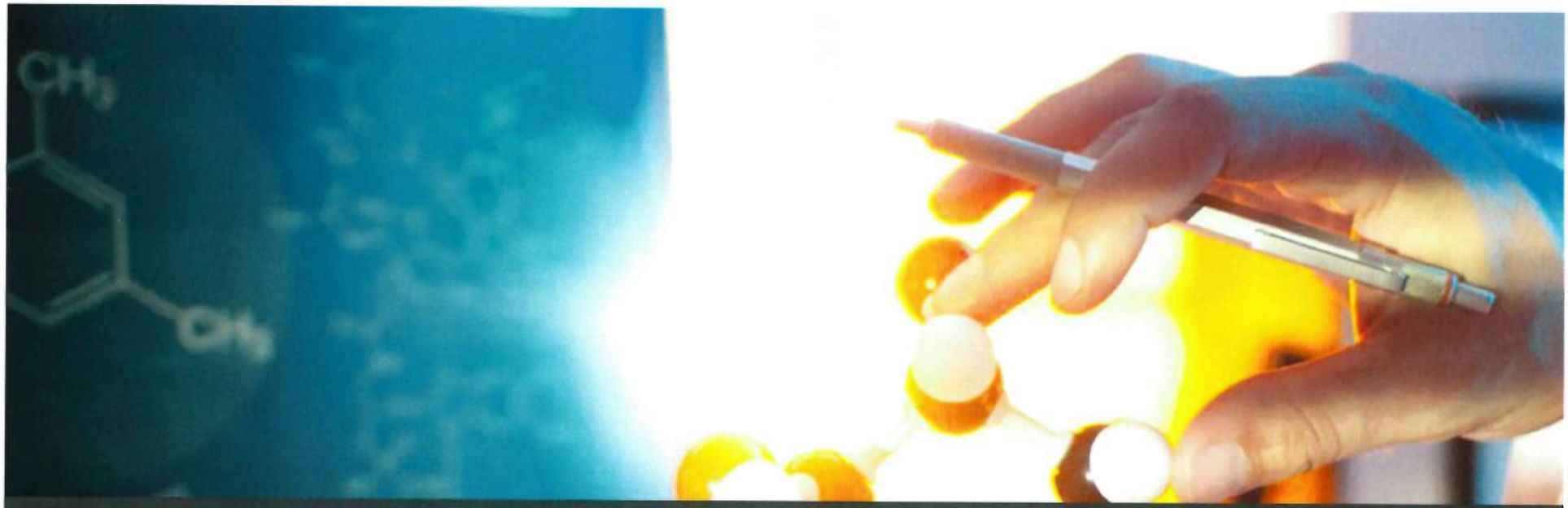

Laboratory Smoking of Flavored and Unflavored Little Cigars and Cigarettes

Use Behavior, Toxicant Exposure, Subjective Effects and Risk Perceptions

Bartosz Koszowski, Ph.D., Pharm.D

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[1] Office of Science, Center for Tobacco Products, Food and Drug Administration

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Disclaimers

- This research was funded by the FDA contract HHSF223201210186C, *Conduct an Experimental Study to Measure the Subjective, Physiological, and Puff Topography Measures, and Perceptions of Flavored Little Cigars.*
- The authors of this presentation have no conflicts of interest to report.
- This presentation is not a formal dissemination of information by FDA and does not represent Agency position or policy

Background

- Cigars, little cigars (LCs), and cigarillos are a class of tobacco products that are newly subject to FDA regulation.
- In the past decade, cigarette sales have decreased while cigar sales have increased.[1]
- A source of increased sales may be use by adolescents who find flavored LCs appealing.
- There are **very few clinical research reports** in the literature on smoking [flavored] cigar products.

[1] Agaku, IT & Alpert, HR. Trends in annual sales and current use of cigarettes, cigars, and roll-your-own tobacco, pipes, and smokeless tobacco among US adults, 2002-2012. *Tob Control* 2015;0:1-8.

Objectives

1. To examine use behavior associated with flavored LCs compared to own brand conventional cigarettes.
2. To assess the influence of flavoring on subjective effects, and compare the subjective effects associated with smoking three LCs (unflavored, menthol, and cherry) relative to each other and to own cigarette brand.
3. To assess health risk perceptions of tobacco products among current dual users of cigarettes and LCs/cigarillos, compare LC product specific characteristics with own brand of cigarettes, and assess the influence of flavoring on risk perceptions.

Overview of Study

48 participants from the Baltimore area; data collection from June 2014 to July 2015.

- All participants were at least 18 years old and were current smokers of at least 10 conventional cigarettes per day and at least one LC or cigarillo per week.

Participants attended 4 laboratory sessions

- Overnight tobacco abstinence confirmed by exhaled breath CO (COex).
- Smoked own brand of cigarette, unflavored, menthol, and cherry LC through CReSS.
- 2 products smoked (separated by 15-20 minute rest period).
- Products weighed before and after smoking.

Measures

- Puff topography and CO exposure
- Subjective effects associated with LC
- Health risk perceptions.

Baseline Characteristics

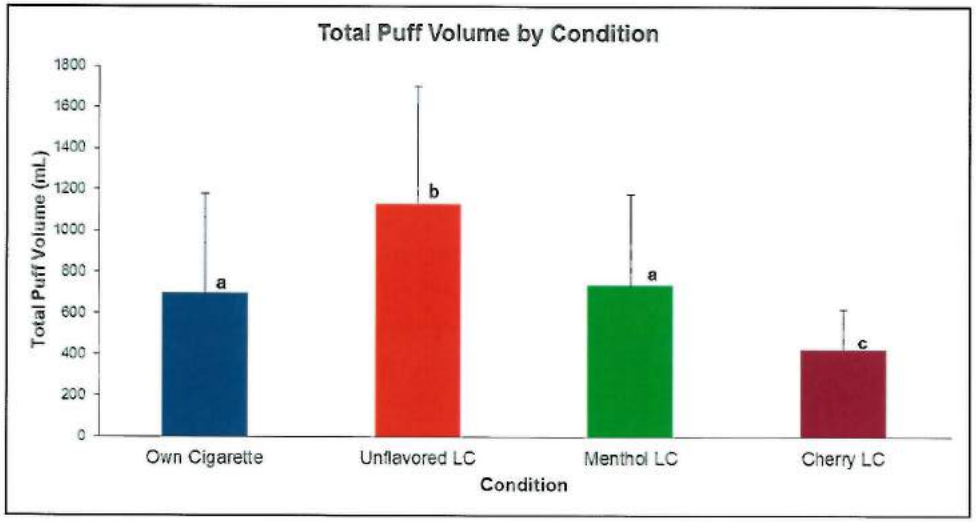
Characteristic	Total (*N*=48) *n* (%)
Race	
Black or African American	36 (75.0)
White	9 (18.8)
Other	3 (6.3)
Gender	
Male	37 (77.1)
Female	11 (22.9)
Age - Mean (*SD*)	39 (9)
Household Income	
<$20,000	33 (68.8)
$20,001-$35,000	10 (20.8)
>$35,000	5 (10.4)

Methods

- Measures of toxicant exposure and use
  - Puff topography and exhaled breath CO (COex)
- Measures of subjective effects
  - Duke Sensory Questionnaire (DSQ)
  - Cigarette Evaluation Scale (CES)
  - Product Specific Risk Questionnaire (PSRQ)
- Measures of health risk perceptions
  - General Risk Perception Questionnaire (GRPQ)
  - Product Specific Risk Questionnaire (PSRQ)
- Statistical analyses controlled for race, nicotine dependence, and age.

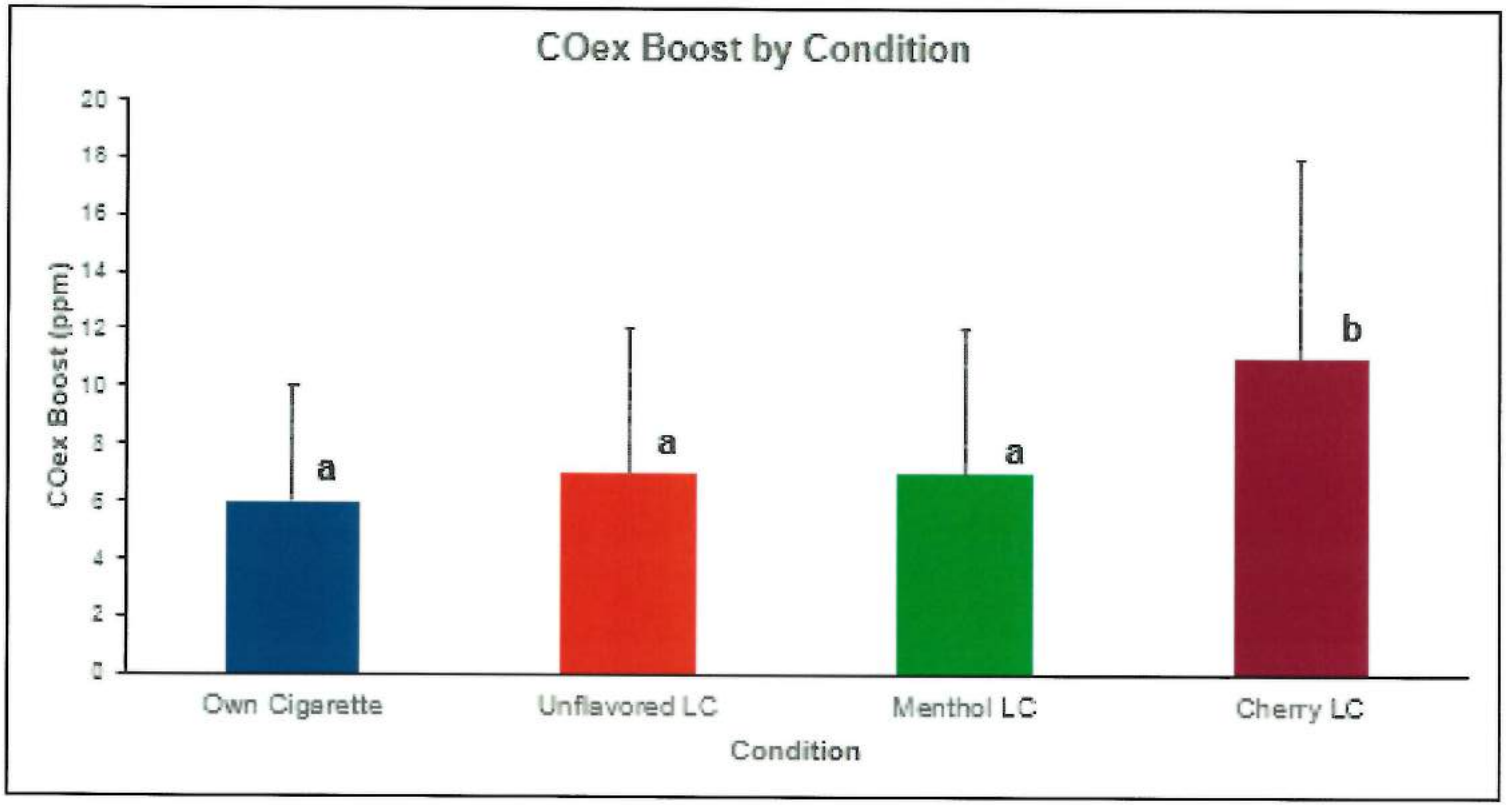
Results – Puff Topography

- Statistical analysis revealed significant between group differences ($p<0.05$) for cigarettes and LCs (unflavored, menthol, cherry, respectively) for:
  - Time to smoke
  - Number of puffs
  - Average puff volume
  - Puff duration
  - Average puff velocity
  - ***Total puff volume***



***NOTE:** Different superscripted letters (in illustrations) indicate significant between-condition differences, $p < 0.05$.*

Results – COex



Results – Subjective Effects

Subjective Effect	Own Cigarette M (SD)	Unflavored LC M (SD)	Menthol LC M (SD)	Cherry LC M (SD)	Collapsed LC M (SD)	p^1
Duke Sensory Questionnaire						
Liking	6.0 (1.2)^{a}	2.9 (1.6)^{b}	2.6 (1.5)^{b}	3.4 (1.7)^{c}	3.0 (1.6)	<0.001
Satisfaction	5.9 (1.2)^{a}	3.1 (1.6)^{b}	2.6 (1.7)^{b}	3.8 (1.9)^{c}	3.2 (1.8)	<0.001
Nicotine	5.7 (1.2)^{a}	4.0 (1.6)^{b}	3.4 (1.7)^{c}	4.6 (1.6)^{d}	4.0 (1.7)	<0.001
Strength	4.8 (1.5)^{a}	3.3 (1.4)^{b}	2.9 (1.4)^{b}	4.0 (1.4)^{c}	3.4 (1.5)	<0.001
Cigarette Evaluation Scale						
Satisfaction	6.2 (1.0)^{a}	2.8 (1.6)^{b}	2.6 (1.7)^{b}	3.5 (1.9)^{c}	3.0 (1.8)	<0.001
Aversion	2.6 (1.5)^{a}	1.6 (0.8)^{b}	1.4 (0.7)^{b}	2.0 (1.1)^{c}	1.7 (0.9)	<0.001
Reward	4.3 (1.4)^{a}	2.4 (1.2)^{b}	2.1 (1.3)^{b}	3.0 (1.3)^{c}	2.5 (1.3)	<0.001
Sensation	5.0 (1.9)^{a}	2.6 (1.5)^{b}	2.5 (1.7)^{b}	3.5 (1.9)^{c}	2.9 (1.8)	<0.001
Craving Reduction	5.8 (1.8)^{a}	3.3 (1.9)^{bc}	2.8 (1.9)^{b}	3.7 (1.9)^{c}	3.3 (1.9)	<0.001
Product Specific Risk Questionnaire						
Overall Positive	81 (18)^{a}	35 (27)^{bc}	33 (24)^{b}	45 (29)^{c}	37 (27)	<0.001
Overall Negative	23 (24)^{a}	54 (32)^{b}	54 (31)^{b}	48 (30)^{b}	52 (31)	<0.001
Smooth	73 (20)^{a}	40 (29)^{b}	45 (31)^{b}	42 (28)^{b}	42 (29)	<0.001
Harsh	25 (22)^{a}	49 (32)^{bc}	42 (33)^{b}	54 (28)^{c}	48 (31)	<0.001
Strong	65 (26)^{ac}	47 (31)^{b}	36 (29)^{b}	64 (23)^{c}	49 (30)	<0.001

Note. Different superscripted letters indicate significant between-condition differences, $p < .05$.
[1]p-value for own cigarette vs. collapsed LC

Results – Subjective Effects

Subjective Effect	Own Cigarette M (SD)	Unflavored LC M (SD)	Menthol LC M (SD)	Cherry LC M (SD)	Collapsed LC M (SD)	p^1
Duke Sensory Questionnaire						
Liking	6.0 (1.2)^a	2.9 (1.6)^b	2.6 (1.5)^b	3.4 (1.7)^c	3.0 (1.6)	<0.001
Satisfaction	5.9 (1.2)^a	3.1 (1.6)^b	2.6 (1.7)^b	3.8 (1.9)^c	3.2 (1.8)	<0.001
Nicotine	5.7 (1.2)^a	4.0 (1.6)^b	3.4 (1.7)^c	4.6 (1.6)^d	4.0 (1.7)	<0.001
Strength	4.8 (1.5)^a	3.3 (1.4)^b	2.9 (1.4)^b	4.0 (1.4)^c	3.4 (1.5)	<0.001
Cigarette Evaluation Scale						
Satisfaction	6.2 (1.0)^a	2.8 (1.6)^b	2.6 (1.7)^b	3.5 (1.9)^c	3.0 (1.8)	<0.001
Aversion	2.6 (1.5)^a	1.6 (0.8)^b	1.4 (0.7)^b	2.0 (1.1)^c	1.7 (0.9)	<0.001
Reward	4.3 (1.4)^a	2.4 (1.2)^b	2.1 (1.3)^b	3.0 (1.3)^c	2.5 (1.3)	<0.001
Sensation	5.0 (1.9)^a	2.6 (1.5)^b	2.5 (1.7)^b	3.5 (1.9)^c	2.9 (1.8)	<0.001
Craving Reduction	5.8 (1.8)^a	3.3 (1.9)^{bc}	2.8 (1.9)^b	3.7 (1.9)^c	3.3 (1.9)	<0.001
Product Specific Risk Questionnaire						
Overall Positive	81 (18)^a	35 (27)^{bc}	33 (24)^b	45 (29)^c	37 (27)	<0.001
Overall Negative	23 (24)^a	54 (32)^b	54 (31)^b	48 (30)^b	52 (31)	<0.001
Smooth	73 (20)^a	40 (29)^b	45 (31)^b	42 (28)^b	42 (29)	<0.001
Harsh	25 (22)^a	49 (32)^{bc}	42 (33)^b	54 (28)^c	48 (31)	<0.001
Strong	65 (26)^{ac}	47 (31)^b	36 (29)^b	64 (23)^c	49 (30)	<0.001

Note. Different superscripted letters indicate significant between-condition differences, $p < .05$.
[1]p-value for own cigarette vs. collapsed LC

Results – Subjective Effects

Subjective Effect	Own Cigarette M (SD)	Unflavored LC M (SD)	Menthol LC M (SD)	Cherry LC M (SD)	Collapsed LC M (SD)	p^1
Duke Sensory Questionnaire						
Liking	6.0 (1.2)^a	2.9 (1.6)^b	2.6 (1.5)^b	3.4 (1.7)^c	3.0 (1.6)	<0.001
Satisfaction	5.9 (1.2)^a	3.1 (1.6)^b	2.6 (1.7)^b	3.8 (1.9)^c	3.2 (1.8)	<0.001
Nicotine	5.7 (1.2)^a	4.0 (1.6)^b	3.4 (1.7)^c	4.6 (1.6)^d	4.0 (1.7)	<0.001
Strength	4.8 (1.5)^a	3.3 (1.4)^b	2.9 (1.4)^b	4.0 (1.4)^c	3.4 (1.5)	<0.001
Cigarette Evaluation Scale						
Satisfaction	6.2 (1.0)^a	2.8 (1.6)^b	2.6 (1.7)^b	3.5 (1.9)^c	3.0 (1.8)	<0.001
Aversion	2.6 (1.5)^a	1.6 (0.8)^b	1.4 (0.7)^b	2.0 (1.1)^c	1.7 (0.9)	<0.001
Reward	4.3 (1.4)^a	2.4 (1.2)^b	2.1 (1.3)^b	3.0 (1.3)^c	2.5 (1.3)	<0.001
Sensation	5.0 (1.9)^a	2.6 (1.5)^b	2.5 (1.7)^b	3.5 (1.9)^c	2.9 (1.8)	<0.001
Craving Reduction	5.8 (1.8)^a	3.3 (1.9)^{bc}	2.8 (1.9)^b	3.7 (1.9)^c	3.3 (1.9)	<0.001
Product Specific Risk Questionnaire						
Overall Positive	81 (18)^a	35 (27)^{bc}	33 (24)^b	45 (29)^c	37 (27)	<0.001
Overall Negative	23 (24)^a	54 (32)^b	54 (31)^b	48 (30)^b	52 (31)	<0.001
Smooth	73 (20)^a	40 (29)^b	45 (31)^b	42 (28)^b	42 (29)	<0.001
Harsh	25 (22)^a	49 (32)^{bc}	42 (33)^b	54 (28)^c	48 (31)	<0.001
Strong	65 (26)^{ac}	47 (31)^b	36 (29)^b	64 (23)^c	49 (30)	<0.001

Note. Different superscripted letters indicate significant between-condition differences, $p < .05$.
[1]p-value for own cigarette vs. collapsed LC

Results – Subjective Effects

Subjective Effect	Own Cigarette M (SD)	Unflavored LC M (SD)	Menthol LC M (SD)	Cherry LC M (SD)	Collapsed LC M (SD)	p^1
Duke Sensory Questionnaire						
Liking	6.0 (1.2)^{a}	2.9 (1.6)^{b}	2.6 (1.5)^{b}	3.4 (1.7)^{c}	3.0 (1.6)	<0.001
Satisfaction	5.9 (1.2)^{a}	3.1 (1.6)^{b}	2.6 (1.7)^{b}	3.8 (1.9)^{c}	3.2 (1.8)	<0.001
Nicotine	5.7 (1.2)^{a}	4.0 (1.6)^{b}	3.4 (1.7)^{c}	4.6 (1.6)^{d}	4.0 (1.7)	<0.001
Strength	4.8 (1.5)^{a}	3.3 (1.4)^{b}	2.9 (1.4)^{b}	4.0 (1.4)^{c}	3.4 (1.5)	<0.001
Cigarette Evaluation Scale						
Satisfaction	6.2 (1.0)^{a}	2.8 (1.6)^{b}	2.6 (1.7)^{b}	3.5 (1.9)^{c}	3.0 (1.8)	<0.001
Aversion	2.6 (1.5)^{a}	1.6 (0.8)^{b}	1.4 (0.7)^{b}	2.0 (1.1)^{c}	1.7 (0.9)	<0.001
Reward	4.3 (1.4)^{a}	2.4 (1.2)^{b}	2.1 (1.3)^{b}	3.0 (1.3)^{c}	2.5 (1.3)	<0.001
Sensation	5.0 (1.9)^{a}	2.6 (1.5)^{b}	2.5 (1.7)^{b}	3.5 (1.9)^{c}	2.9 (1.8)	<0.001
Craving Reduction	5.8 (1.8)^{a}	3.3 (1.9)^{bc}	2.8 (1.9)^{b}	3.7 (1.9)^{c}	3.3 (1.9)	<0.001
Product Specific Risk Questionnaire						
Overall Positive	81 (18)^{a}	35 (27)^{bc}	33 (24)^{b}	45 (29)^{c}	37 (27)	<0.001
Overall Negative	23 (24)^{a}	54 (32)^{b}	54 (31)^{b}	48 (30)^{b}	52 (31)	<0.001
Smooth	73 (20)^{a}	40 (29)^{b}	45 (31)^{b}	42 (28)^{b}	42 (29)	<0.001
Harsh	25 (22)^{a}	49 (32)^{bc}	42 (33)^{b}	54 (28)^{c}	48 (31)	<0.001
Strong	65 (26)^{ac}	47 (31)^{b}	36 (29)^{b}	64 (23)^{c}	49 (30)	<0.001

Note. Different superscripted letters indicate significant between-condition differences, $p < .05$.
[1]p-value for own cigarette vs. collapsed LC

Results – Subjective Effects

Subjective Effect	Own Cigarette M (SD)	Unflavored LC M (SD)	Menthol LC M (SD)	Cherry LC M (SD)	Collapsed LC M (SD)	p^1
Duke Sensory Questionnaire						
Liking	6.0 (1.2)^{a}	2.9 (1.6)^{b}	2.6 (1.5)^{b}	3.4 (1.7)^{c}	3.0 (1.6)	<0.001
Satisfaction	5.9 (1.2)^{a}	3.1 (1.6)^{b}	2.6 (1.7)^{b}	3.8 (1.9)^{c}	3.2 (1.8)	<0.001
Nicotine	5.7 (1.2)^{a}	4.0 (1.6)^{b}	3.4 (1.7)^{c}	4.6 (1.6)^{d}	4.0 (1.7)	<0.001
Strength	4.8 (1.5)^{a}	3.3 (1.4)^{b}	2.9 (1.4)^{b}	4.0 (1.4)^{c}	3.4 (1.5)	<0.001
Cigarette Evaluation Scale						
Satisfaction	6.2 (1.0)^{a}	2.8 (1.6)^{b}	2.6 (1.7)^{b}	3.5 (1.9)^{c}	3.0 (1.8)	<0.001
Aversion	2.6 (1.5)^{a}	1.6 (0.8)^{b}	1.4 (0.7)^{b}	2.0 (1.1)^{c}	1.7 (0.9)	<0.001
Reward	4.3 (1.4)^{a}	2.4 (1.2)^{b}	2.1 (1.3)^{b}	3.0 (1.3)^{c}	2.5 (1.3)	<0.001
Sensation	5.0 (1.9)^{a}	2.6 (1.5)^{b}	2.5 (1.7)^{b}	3.5 (1.9)^{c}	2.9 (1.8)	<0.001
Craving Reduction	5.8 (1.8)^{a}	3.3 (1.9)^{bc}	2.8 (1.9)^{b}	3.7 (1.9)^{c}	3.3 (1.9)	<0.001
Product Specific Risk Questionnaire						
Overall Positive	81 (18)^{a}	35 (27)^{bc}	33 (24)^{b}	45 (29)^{c}	37 (27)	<0.001
Overall Negative	23 (24)^{a}	54 (32)^{b}	54 (31)^{b}	48 (30)^{b}	52 (31)	<0.001
Smooth	73 (20)^{a}	40 (29)^{b}	45 (31)^{b}	42 (28)^{b}	42 (29)	<0.001
Harsh	25 (22)^{a}	49 (32)^{bc}	42 (33)^{b}	54 (28)^{c}	48 (31)	<0.001
Strong	65 (26)^{ac}	47 (31)^{b}	36 (29)^{b}	64 (23)^{c}	49 (30)	<0.001

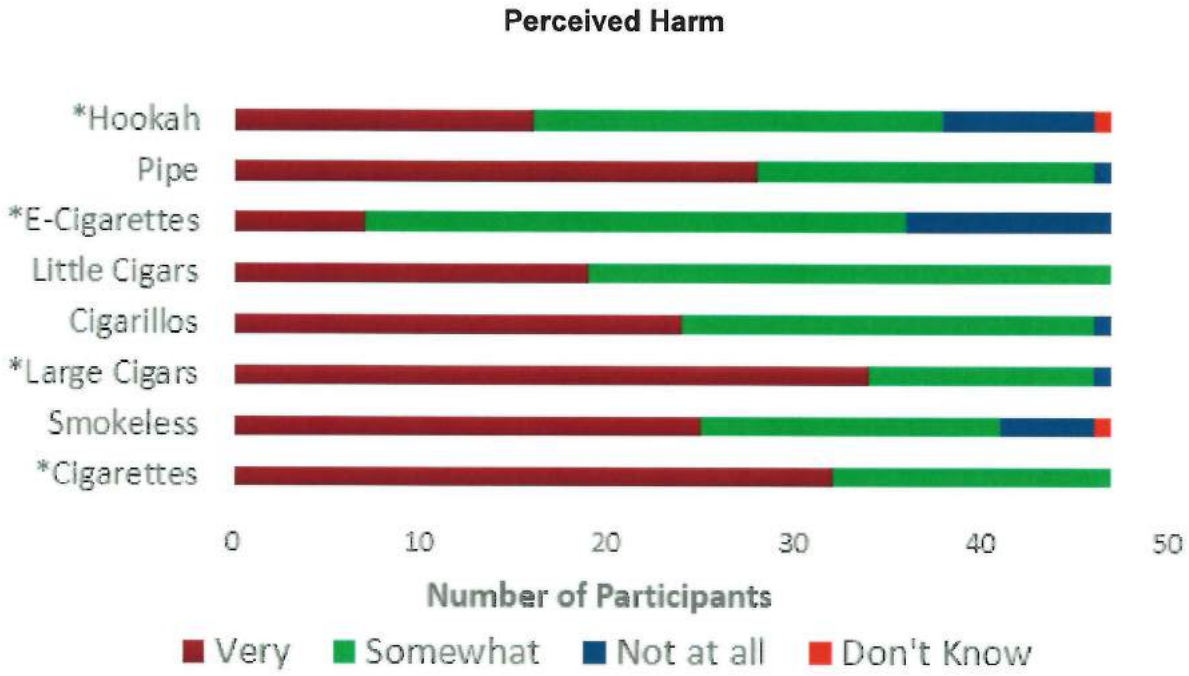
Note. Different superscripted letters indicate significant between-condition differences, $p < .05$.
[1]p-value for own cigarette vs. collapsed LC

Results – Subjective Effects

Subjective Effect	Own Cigarette M (SD)	Unflavored LC M (SD)	Menthol LC M (SD)	Cherry LC M (SD)	Collapsed LC M (SD)	p^1
Duke Sensory Questionnaire						
Liking	6.0 (1.2)^{a}	2.9 (1.6)^{b}	2.6 (1.5)^{b}	3.4 (1.7)^{c}	3.0 (1.6)	<0.001
Satisfaction	5.9 (1.2)^{a}	3.1 (1.6)^{b}	2.6 (1.7)^{b}	3.8 (1.9)^{c}	3.2 (1.8)	<0.001
Nicotine	5.7 (1.2)^{a}	4.0 (1.6)^{b}	3.4 (1.7)^{c}	4.6 (1.6)^{d}	4.0 (1.7)	<0.001
Strength	4.8 (1.5)^{a}	3.3 (1.4)^{b}	2.9 (1.4)^{b}	4.0 (1.4)^{c}	3.4 (1.5)	<0.001
Cigarette Evaluation Scale						
Satisfaction	6.2 (1.0)^{a}	2.8 (1.6)^{b}	2.6 (1.7)^{b}	3.5 (1.9)^{c}	3.0 (1.8)	<0.001
Aversion	2.6 (1.5)^{a}	1.6 (0.8)^{b}	1.4 (0.7)^{b}	2.0 (1.1)^{c}	1.7 (0.9)	<0.001
Reward	4.3 (1.4)^{a}	2.4 (1.2)^{b}	2.1 (1.3)^{b}	3.0 (1.3)^{c}	2.5 (1.3)	<0.001
Sensation	5.0 (1.9)^{a}	2.6 (1.5)^{b}	2.5 (1.7)^{b}	3.5 (1.9)^{c}	2.9 (1.8)	<0.001
Craving Reduction	5.8 (1.8)^{a}	3.3 (1.9)^{bc}	2.8 (1.9)^{b}	3.7 (1.9)^{c}	3.3 (1.9)	<0.001
Product Specific Risk Questionnaire						
Overall Positive	81 (18)^{a}	35 (27)^{bc}	33 (24)^{b}	45 (29)^{c}	37 (27)	<0.001
Overall Negative	23 (24)^{a}	54 (32)^{b}	54 (31)^{b}	48 (30)^{b}	52 (31)	<0.001
Smooth	73 (20)^{a}	40 (29)^{b}	45 (31)^{b}	42 (28)^{b}	42 (29)	<0.001
Harsh	25 (22)^{a}	49 (32)^{bc}	42 (33)^{b}	54 (28)^{c}	48 (31)	<0.001
Strong	65 (26)^{ac}	47 (31)^{b}	36 (29)^{b}	64 (23)^{c}	49 (30)	<0.001

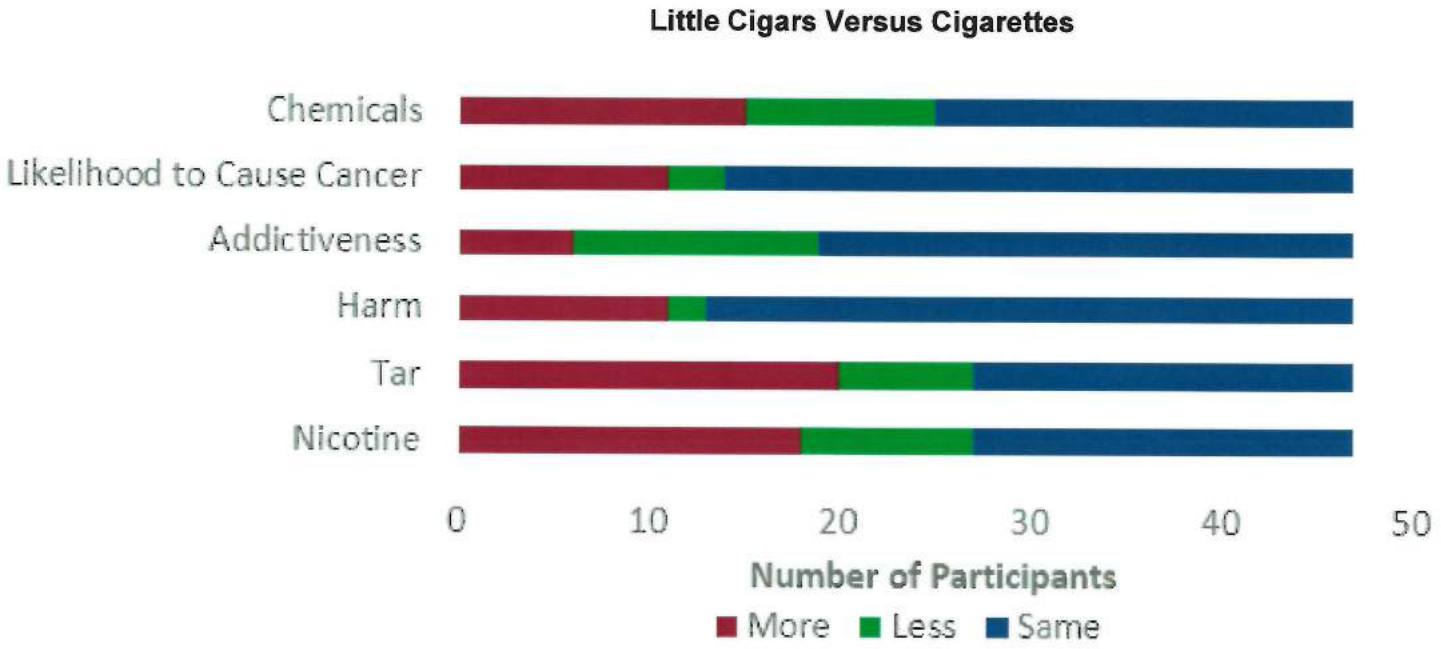
Note. Different superscripted letters indicate significant between-condition differences, $p < .05$.
[1]p-value for own cigarette vs. collapsed LC

Results – General Risk Perception Questionnaire

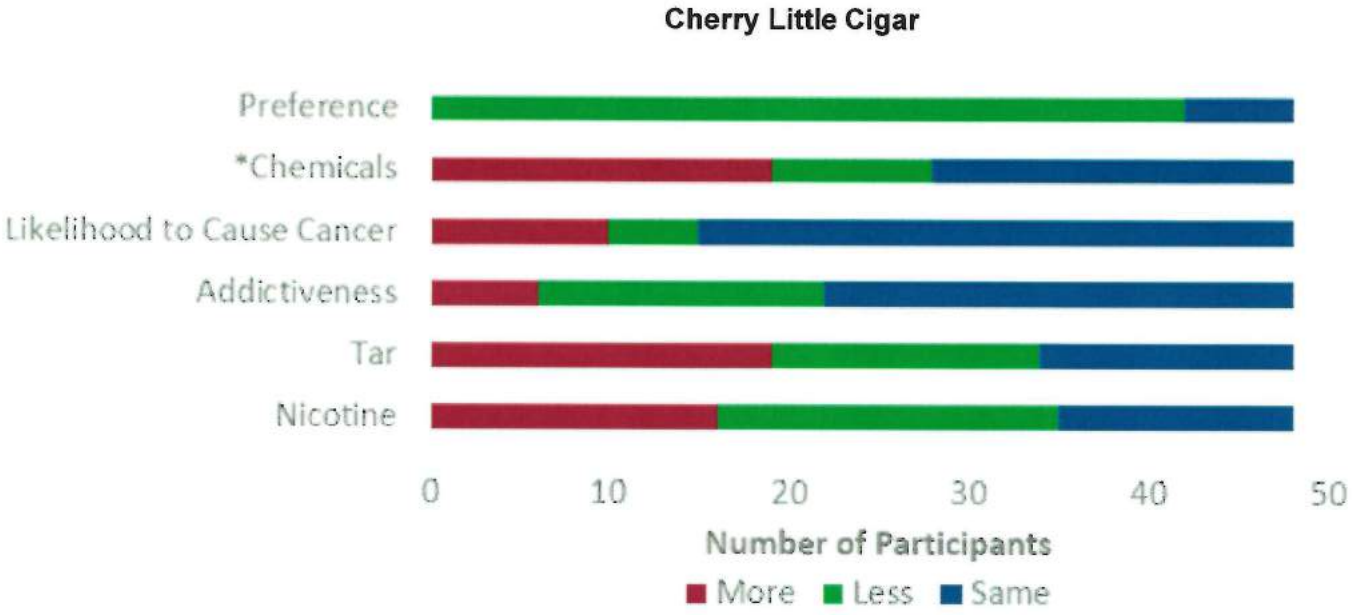


** Indicates significant difference between 'Very' and 'Somewhat'/ 'Not at all' at p<.05*

Results – General Risk Perception Questionnaire



Results – Product Specific Risk Questionnaire



** After smoking the cherry LC, significantly more people thought cherry LCs had 'more' chemicals compared to the other LCs ($p<.05$).*

Conclusions

- Puff topography and COex
  - Relative to smoking own brand cigarettes, smoking cherry LCs was associated with a higher boost in COex in spite of being associated with a smaller amount of tobacco smoked.
  - Relative to unflavored and menthol LCs, cherry flavored LCs were associated with the highest boost in COex, yet lowest in puff volume.
  - Despite a smaller amount of tobacco smoked and lowest puff volume, cherry LC smoking was associated with the highest exposure to CO.

Conclusions (con't)

- Subjective Effects
  - Own cigarettes were reported as more appealing than LCs among adult dual users across all categories of subjective effects.
  - Flavors in LCs, especially cherry, produced differences in subjective ratings related to appeal.
- Health Risk Perceptions
  - Dual users of cigarettes and cigar products report that there are different levels of risk associated with various tobacco products.
  - Participants were much more certain about health risks of cigarette use compared to other tobacco products.

Future Directions

- Future studies should examine whether results generalize to individuals who are naïve to LC use.
- Is there something about the cherry flavor or would other "unfamiliar flavors" give similar results?
- Are there differences in flavor preference as a function of gender, age and smoking experience?
- Some LC products are ventilated – how does the design impact the exposure?

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From: Ibarra-Pratt, Ele
To: Villa, Anthony; Kabaria, Swati
Subject: FW: Cheyenne Warning Letter
Date: Tuesday, May 23, 2017 3:47:22 PM
Attachments: Cheyenne- FOIA Request_1 (3).DOCX

From: Scheineson, Marc [mailto:Marc.Scheineson@alston.com]
Sent: Tuesday, May 23, 2017 3:46 PM
To: Mednick, David; Simoneau, Ann; Ibarra-Pratt, Ele
Cc: David Scott; Ralph Brown; Carroll, Brendan
Subject: Cheyenne Warning Letter

Per our recent meeting, and at your suggestion, attached is a copy of the FOIA request for the CTP-OS Customer Confusion study you described. A hard copy has been sent to the FOIA Office and the Document Center. We hope you will work cooperatively with the CTP FOIA office to make this study available quickly so we can proceed in the resolution of this matter. Happy to discuss further. Best, Marc.

Marc J. Scheineson, Esq.
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(202) 344-5848 (Mobile)
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2017-4124

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May 23, 2017

VIA FAX (301) 827-9267
Original Sent by U.S. Mail

U.S. Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5630 Fishers Lane, Room 1035
Rockville, MD 20857

MAY 24 2017

Commercial ____
Nonprofit/Media ____
Other ____

Re: **FOIA Request for FDA-CTP Office of Science "Study that Supports the December 9, 2016 Warning Letter" issued to Cheyenne International LLC**

To Whom It May Concern:

Alston & Bird LLP represents Cheyenne International LLC (Cheyenne). In that capacity, we request information from the U.S. Food and Drug Administration (FDA) pursuant to 21 C.F.R. §20.40 and the Freedom of Information Act (FOIA), 5 U.S.C. §552. We request **expedited processing** and delivery of the requested documents for the reasons stated below. Since the request is a narrow one, if expedited processing is denied, we would appreciate your working cooperatively with FDA's Center for Tobacco Products (CTP) to make these documents available as quickly as possible.

On December 9, 2016, FDA-CTP issued a Warning Letter to Cheyenne and three other companies (Prime Time International Distributing, Inc.; Southern Cross Tobacco Company, Inc.; and Swisher International LLC). The letter alleged that certain small flavored filtered cigars manufactured by these companies are, in the Agency's view, cigarettes under the definition provided in §900(3) of the Federal Food, Drug and Cosmetic Act (FDCA). This interpretation could make the products "adulterated' since cigarettes, unlike cigars, are prohibited from containing characterizing flavors other than menthol.

On May 10, 2017, during a meeting requested by FDA-CTP, the agency disclosed that the basis of this Warning Letter was a "consumer confusion" study conducted by FDA-CTP's Office of Science. FDA did not provide specific details regarding the formal name of the study, the authors, applicable dates, or other identifying information. It stated that Cheyenne could request this study, and related documents, under the Freedom of

CTP

Information Act (FOIA) by referencing the "Study that Supports the December 9, 2016 Warning Letter" issued to Cheyenne and three other cigar manufacturers.

Below is information specific to this request:

a. Requestor. Marc J. Scheineson, Esq., Alston & Bird LLP, 950 F Street, NW, 9th Floor, Washington, DC 20004; telephone: 202-239-3465; fax: 202-654-4838; email: marc.scheineson@alston.com.

b. Description of the Records Sought. The following materials are requested which, in the interest of time, may be provided to us on a **rolling or staggered basis** as they are obtained and reviewed:

- A complete and accurate copy of the "Study that Supports the December 9, 2016 CTP Warning Letter" concerning the sale of flavored filtered cigars including all methodology, raw data, eligibility criteria, background of participants, case reports, interview logs, questionnaires, tabulated responses, video recordings, analysis, commentary, interpretation, conclusions, and related communications. This study, conducted by the CTP Office of Science, reportedly enrolled and interviewed consumers by presenting packages of flavored filtered cigars, and questioned whether the packaged products were cigarettes or cigars. Other portions of the research may have permitted subjects to open the packages and examine the product sticks, and perhaps even ignite the products, or otherwise sample the contents of the packaging.

- Identification information pertaining to the study, including, but not limited to: the name of the study; the authors of the study, and their affiliations (including any affiliation with FDA); any requests for proposals (RFPs) issued by FDA; the date the study was commissioned, and the dates that any reports were published; any information pertaining to funding of the study, any conflict-of-interest statements or other related information; name, title, experience and qualifications of investigators who were responsible for conducting the research; name and address of any clinical laboratories and other institutions involved in the research; and any other information identifying the study and establishing the basis for its commission.

- Any and all associated study documentation, including, but not limited to:

  - study protocols, including any and all relevant information about study goals and objectives, study design and methodology, study parameters, subjects and research population, length and duration of the study and inclusion/exclusion criteria.

  - laboratory testing methods, testing results, data, outcome and any other findings of the study related to all brands tested and to Cheyenne in particular.

- information pertaining to the dissemination of results and publication of the study.

Alston & Bird will pay all requisite costs and fees, without limitation, related to the costs of processing this request and producing copies of these materials. Documents can be forwarded to me as they become available, via PDF and email at marc.scheineson@alston.com, or can be faxed to my attention at (202) 239-3333, or may be mailed via overnight courier to the address listed above. We will also pay the cost of shipping.

Unless Cheyenne receives the materials requested as expeditiously as possible, it may not have an adequate opportunity to respond in full to the pending enforcement action initiated by FDA-CTP. Our client will lose substantial due process rights if it does not receive the requested essential documents in time to use them as it prepares its supplemental response to the issued Warning Letter as requested in the meeting with CTP. *See* criteria for expedited responses including: *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976), *citing* 5 U.S.C. §552(a)(6)(c)(some FOIA requests necessarily involve a far greater degree of urgency than others, and that when a requester can show "exceptional need or urgency," the request should be processed on an expedited basis).

As contemplated by §552(a), we expect to receive a response within 10 working days to our request for expedited processing. Also, as you are aware, a determination letter is required within 20 working days after the request is logged, 21 C.F.R. §20.41(b). If for any reason you decide to withhold (e.g., not produce) a document or a portion of a document, the determination letter shall also disclose the legal and factual bases for any decision to deny disclosure.

Thank you for your assistance. We appreciate your production of these documents as soon as possible and on a rolling basis, or in a complete file, as appropriate. If you have any questions regarding this request, please call me at 202-239-3465, or contact me at marc.scheineson@alston.com.

Sincerely,

Marc J. Scheineson

cc: Ann Simoneau, Esq. (via email)
David Mednick, Esq. (via email)
Mr. David Scott (via email)
Mr. Ralph Brown (via email)

ALSTON&BIRD LLP

The Atlantic Building
950 F Street, NW
Washington, DC 20004-1404
202-239-3300
Fax: 202-654-4838

TELECOPY

PLEASE DELIVER AS SOON AS POSSIBLE

Date:
May 23, 2017

Recipient:
U.S. Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5630 Fishers Lane, Room 1035
Rockville, MD 20857

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

Fax Number: 301-827-9267

Voice Numbe r:

Sender:
Marc J. Scheineson

Message:

Please see the attached FOIA Request for FDA-CTP Office of Science "St udy that Supports the December 9, 2016 Warning Letter" issued to Cheyenne International LLC.

Number of Pages: (including cover pa ge) 4

IF NOT RECEIVED PROPERLY, PLEASE NOTIFY ME IMMEDIATEL Y AT 202-239-3300

USER CODE: SCHEM	REQUESTED BY: Marc J Scheineson
CLIENT/MATTER:	FAX OPERATOR:

CENTER FOR TOBACCO PRODUCTS

MAR 2 3 2018

VIA UPS

David A. Scott
Chief Executive Officer
Cheyenne International, LLC
701 S. Battleground Ave.
Grover, NC 28073

RE: Warning Letter issued to Cheyenne International, LLC (RW1600609)

Dear Mr. Scott:

On December 9, 2016, the United States Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) issued you a Warning Letter for the sale or distribution of flavored cigarette products in violation of section 907(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA determined that your Cheyenne 100's Wild Cherry products labeled as "cigars" meet the FD&C Act's definition of "cigarettes" and that the products were consequently either adulterated under section 902(5) of the FD&C Act, or misbranded under section 903(a)(7)(A) of the FD&C Act.

On December 30, 2016, you sent FDA a response to the Warning Letter, and we met on May 10, 2017 to discuss the Warning Letter and your response. In addition, on June 20, 2017, you sent FDA a letter regarding the meeting.

On March 29, 2017, you submitted Cheyenne's cigar warning plan, which you amended on January 30, 2018, under the cigar warning statement requirements of 21 C.F.R. §1143.5. Your submission included samples of labeling and advertising with the new required warning statements for cigars.

Based on our evaluation of your new proposed labeling and advertising, it appears that once you amend your product labeling and advertising to include the required warning statements for cigars, you will have addressed the violations identified in the Warning Letter.

FDA will verify your implementation and use of the new required warning statements for cigars on your product labeling and advertising at your next inspection and will subsequently issue a close-out letter after FDA has confirmed that your products are in compliance with the FD&C Act. This letter does not relieve you or your firm from the responsibility of taking all necessary steps to ensure sustained compliance with the FD&C Act and its implementing regulations or with other relevant legal authority.

Should you have any questions or concerns, please contact Ele Ibarra-Pratt at (301) 796-9235 or by email at elenita.ibarrapratt@fda.hhs.gov.

Sincerely,

Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products

VIA UPS

cc:

Ralph S. Brown
Vice President, Governmental Affairs
Cheyenne International, LLC
701 S. Battleground Ave.
Grover, NC 28073

Marc J. Scheineson, Esq.
Alston & Bird LLP
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950 F Street, NW
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