

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED

SEP 22 2009

CIVIL N Clerk, U.S. District and
Bankruptcy Courts

Case: 1:09-cv-01835
Assigned To : Kollar-Kotelly, Colleen
Assign. Date : 9/22/2009
Description: TRO/PI

KRETEK INTERNATIONAL, INC.,)
5449 Endeavour Court,)
Moorpark, CA 33351)
Plaintiff,)

vs.)

U.S. FOOD AND DRUG ADMINISTRATION,)
and)
MARGARET HAMBURG, Commissioner of)
the United States Food and Drug)
Administration)
10903 New Hampshire Avenue)
Silver Spring, MD 20903)

and)

U.S DEPARTMENT OF HEALTH AND)
HUMAN SERVICES, and)
KATHLEEN SEBELIUS, Secretary of the)
United States Department of Health and Human)
Services,)
200 Independence Avenue, S.W.)
Washington, DC 20201,)
Defendants.)

COMPLAINT

INTRODUCTION

1. This action involves a dispute over whether the FDA's authority to regulate *cigarettes* with certain "characterizing flavors" also authorizes the FDA to regulate flavored *cigars* (including Djarum brand cigars) under The Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, Section 900(3)(A) (the "Act"), despite the fact that there has been a clear distinction between cigars and cigarettes for 30 years, that Djarum cigars clearly qualify as

“cigars” under this accepted definition, and in fact, the United States Department of Treasury has tested the products and determined and acknowledged that Djarum cigars are cigars and not cigarettes.

PARTIES

2. Plaintiff Kretek International, Inc. (“Kretek”) is a California corporation with a principal place of business at 5449 Endeavour Court, Moorpark, CA 93021. Kretek is an importer and distributor of tobacco products. Kretek is the exclusive importer of Djarum brand cigars.

3. Defendant United States Food and Drug Administration (“FDA”) is a federal agency of the United States, within the United States Department of Health and Human Services. The FDA’s headquarters are located in Silver Spring, Maryland. Defendant Margaret Hamburg is the Commissioner of the FDA.

4. Defendant United States Department of Health and Human Services (“HHS”) is a federal agency of the United States, located in Washington, DC. Defendant Kathleen Sebelius is the Secretary of HHS.

5. This Court has subject matter jurisdiction over Plaintiff’s claims pursuant to 28 U.S.C. § 1331. Declaratory relief is authorized by 28 U.S.C. § 2201 and 2202.

6. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

FACTUAL ALLEGATIONS

The Family Smoking Prevention and Tobacco Control Act

7. The Act was signed into law on June 22, 2009. Among other things, the Act prohibited cigarettes from containing certain “characterizing flavors.” The Act’s prohibition on “characterizing flavors,” however, only applies to cigarettes. *See* Pub. L. 111-31, Section

907(a)(1)(A) (“Special Rule for Cigarettes”). Cigars with a “characterizing flavor” are not prohibited by the new law.

8. Congress gave the FDA authority to regulate a variety of tobacco products after implementation of certain rulemaking procedures. But the FDA’s initial authority is limited to “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco” – not cigars. *See* Pub. L. 111-31, Section 901(b). The FDA has not promulgated any rules or regulations regarding cigars. Therefore, the FDA has no authority to regulate cigars.

9. The Act relies upon and incorporates the historic distinction between cigars and cigarettes which was included in prior Acts of Congress and administrative regulations.

10. The Act provides that the term “cigarette”:

(A) means 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

(B) 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.

See Pub. L. No. 111-31, Section 900(3)(A).

11. The Act also refers to cigars and little cigars as a separate classification of tobacco products than cigarettes. *See* Pub. L. No. 111-31, Section 900(3)(11) (defining “little cigar” identical to the definition in the Federal Cigarette Labeling and Advertising Act of 1965 (“FCLAA”) as amended by the Little Cigar Act); Section 919(b)(2)(B) (distinguishing between cigarettes and cigars, including large and small cigars).

12. Several prior acts of Congress defined and distinguished between cigarettes and cigars. The definition of cigarette in the Act is almost identical to the definition of cigarette in the FCLAA and the Treasury Department’s tax code provisions (“Tax Code Provisions”).

Compare Pub. L. No. 111-31, Section 900(3)(A) with 15 U.S.C. § 1332(1) and 26 U.S.C. § 5702.

13. The statutory definitions of cigars and cigarettes are mutually exclusive. If a product is a cigar, it is not a cigarette, and vice versa.

14. In the 1970's, pursuant to its authority under the Tax Code Provisions, the Alcohol and Tobacco Tax and Trade Bureau ("TTB") issued detailed regulations distinguishing between cigarettes and cigars. *See* ATF Ruling 73-22 and Procedures 73-5 and 76-2.

15. The TTB's well-known distinction between a cigarette and cigar depends upon a number of factors, including the type of tobacco used in the filler (flue-cured versus air-cured), the type of wrapper (paper versus tobacco leaf), the weight of the product, and packaging of the product (whether the product is labeled a cigarette or a cigar). *See* ATF Ruling 73-22 and Procedures 73-5 and 76-2.

16. With a full understanding of the longstanding distinction between cigarettes and cigars, Congress defined "cigarette" in the Act in the same manner that it had before in the FCLAA and Tax Code Provisions.

Djarum Cigars

17. Kretek imports several brands of cigars, including: Djarum Mild, Djarum Special, Djarum Black Filter, Djarum Splash, Djarum Bali Hai, Djarum Black Cherry and Djarum Black Vanilla (collectively "Djarum Cigars").

18. Each of these Djarum Cigars is a cigar, and none is a cigarette.

19. Djarum Cigars contain air-cured, not flue-cured, tobacco.

20. The tobacco in Djarum Cigars is cigar tobacco, not a cigarette tobacco.

21. The reducing sugars content of Djarum Cigars is consistent with the reducing sugar content in other cigars and inconsistent with the reducing sugar content of cigarettes.

22. Djarum Cigars are wrapped in homogenized tobacco leaf product, similar to other filtered cigars, not in paper like cigarettes.

23. Djarum Cigars weigh more than 3 lbs per 1,000 units, thus exceeding the weight for standard cigarettes. In fact Djarum Cigars exceed the weight limitation for “little cigars,” which is the product most commonly confused with cigarettes. Djarum Cigars are not “little cigars.” They are regular, standard cigars.

24. Djarum Cigars are conspicuously labeled as cigars. The word cigar appears no less than eight times on the packaging of the cigars.

25. Djarum Cigars are sold in packages of 12, whereas cigarettes are always packaged in 20-count packs.

26. For the Djarum Cigars, Kretek submitted samples of the products and packaging to the TTB to request that the TTB provide a ruling regarding whether the products qualified as cigars or cigarettes. After conducting laboratory analyses of the products and evaluations of the packaging, labeling and intended use of the products, the TTB determined that these Djarum Cigars are cigars (not cigarettes) under the current definition. The TTB stated that the Djarum Cigars were “consistent with the current analytic profile of a cigar, specifically a large cigar, and is properly classified as such for tax and regulatory purposes.” (See Department of Treasury Letters, Exhibit A).

27. As early as September 24, 2007, Kretek received approval from the TTB to sell and market certain brands of these Djarum Cigars. Approval for other brands came later.

The FDA's Unlawful Attempt To Expand The Definition Of "Cigarette"

28. The Act's ban on cigarettes with certain "characterizing flavors" takes effect September 22, 2009.

29. On September 14, 2009, the FDA published a "Letter to Industry on Cigarettes Containing Certain Characterizing Flavors." That letter stated that the ban on "characterizing flavors" "applies to all tobacco products that meet the definition of 'cigarette' in section 900(3) of the Act *even if they are not labeled as 'cigarettes' or are labeled as cigars or as some other product.*" (FDA September 14, 2009 letter available at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm182186.htm>). Upon information and belief, the FDA has made other similar statements and innuendo to the marketplace suggesting that it intends to attempt to regulate Djarum Cigars and other cigars as "cigarettes" under the Act.

30. By suggesting that tobacco products that are classified by TTB to be cigars can somehow be cigarettes under the Act, the FDA has deliberately obfuscated the clarity of the uniform definition of cigarette in the FCLAA, TTB's Tax Code Provisions and the Act.

31. The FDA's letter and other threats have caused tremendous confusion and uncertainty in the cigar industry because of fear that the FDA intends to treat cigars as cigarettes, despite the well-established and long-standing distinction between the two categories of products.

32. Because of this uncertainty, several trade associations petitioned the FDA to clarify its position regarding the distinction between cigars and cigarettes before the September 22, 2009 effective date of the Act or in the alternative to exercise enforcement discretion until it did so, but the FDA refused to do either one.

33. Consequently, Kretek and its distributors and retailers are fearful that the FDA intends to treat Djarum Cigars as cigarettes under the Act, and to seize Djarum Cigars, and otherwise take efforts to restrict sales of such cigars, or impose civil penalties for continued sales of such cigars.

34. Given the FDA's threats and the potential civil penalties at issue, Kretek is entitled to a declaratory judgment ruling that Djarum Cigars are not "cigarettes" under the Act, and that the FDA has no legal right to regulate Djarum Cigars under the Act.

35. If Kretek's Djarum Cigars are seized by the FDA or Kretek and its distributors and retailers are otherwise precluded from selling Djarum Cigars, the damage to Kretek's business will be irreparable.

36. Kretek is already being irreparably harmed as a result of FDA's threats because it has prevented Kretek from adequately planning for importing, warehousing and distributing Djarum Cigars in the normal course of business. It takes at least four to six months to plan for the distribution chain from Indonesia (where the cigars are manufactured) to the United States. Kretek cannot adequately manage this supply chain given the threat that the FDA may, at any moment, unlawfully declare that Djarum Cigars are cigarettes.

37. Upon information and belief, Kretek is also being irreparably harmed as a result of the FDA's threats because retailers and distributors are less likely to purchase Djarum cigars.

38. Consequently, Kretek is also entitled to a temporary restraining order, preliminary injunction, and permanent injunction, precluding the FDA from regulating Djarum Cigars under the Act, and further precluding the FDA from seizing any Djarum Cigars or otherwise attempting to interfere with sales of such cigars.

**COUNT I:
DECLARATORY JUDGMENT**

39. Kretek incorporates paragraphs 1 - 38 above by reference as if fully set forth herein.

40. Upon information and belief, Defendants contend that Djarum Cigars are “cigarettes” under the Act, despite the fact that Djarum Cigars meet all of the requirements for cigars and are classified as cigars by the TTB. Kretek contends that Djarum Cigars are cigars. Consequently, there is an actual and justiciable controversy between Plaintiff and Defendants regarding whether Djarum Cigars fall within the definition of “cigarette” in the Act.

41. Further, Defendants’ threats to the marketplace have created uncertainty regarding Kretek’s and others’ ability to continue selling Djarum Cigars, as well as whether the FDA will attempt to seize such cigars or impose civil penalties for sales of such cigars.

42. Kretek is entitled to a judicial ruling declaring that each of the Djarum Cigars is a cigar and not a cigarette, and, therefore, the Act’s ban on “characterizing flavors” does not apply to Djarum Cigars.

43. Kretek is further entitled to a judicial ruling declaring that Defendants have no legal right to regulate Djarum Cigars as cigarettes under the Act.

**COUNT II
The FDA’s Assertion Of Authority Over Djarum Cigars Is *Ultra Vires***

44. Kretek incorporates paragraphs 1 - 43 above by reference as if fully set forth herein.

45. The FDA has no authority under the Act to ban any type of cigar without first promulgating rules and regulations establishing such authority.

46. The FDA has not promulgated any rules or regulations with respect to cigars.

47. Djarum Cigars are cigars.

48. Therefore, the FDA has no authority over Djarum Cigars and cannot take any enforcement action with respect to Djarum Cigars.

49. The FDA's attempt to assert jurisdiction over Djarum Cigars is "in excess of statutory jurisdiction, authority, or limitations of statutory right." 5 U.S.C. § 706(2).

COUNT III
Injunctive Relief

50. Kretek incorporates paragraphs 1 – 49 above by reference as if fully set forth herein.

51. Kretek is likely to succeed on the merits of this dispute.

52. If, however, the FDA is allowed to regulate Djarum Cigars under the Act, to seize Djarum Cigars, or to otherwise interfere with sales of such cigars, Kretek will suffer immediate and irreparable harm for which there is no adequate remedy at law.

53. Kretek therefore requests that the court enter a temporary restraining order, preliminary injunction, and permanent injunction prohibiting the FDA from seizing Djarum Cigars, issuing an Import Alert against Djarum Cigars, making statements to the public or the industry that Djarum Cigars are banned, or taking any other action adverse to Kretek with respect to Djarum Cigars on the basis that such products are banned by the Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. enter a judgment declaring that each of the Djarum Cigars is a cigar and not a cigarette, and, therefore, the Act's ban on "characterizing flavors" does not apply to Djarum Cigars;


B. enter a judgment declaring that the FDA has no authority over Djarum Cigars, or any other cigars imported by Kretek that have been previously approved by the TTB, and cannot take any enforcement action with respect to Djarum Cigars;

C. enter a temporary restraining order, preliminary injunction and permanent injunction prohibiting the FDA from seizing Djarum Cigars, issuing an Import Alert against Djarum Cigars, making statements to the public or the industry that Djarum Cigars are banned, or taking any other action adverse to Kretek with respect to Djarum Cigars on the basis that such products are banned by the Act;

D. grant Plaintiff such additional or different relief as it deems just and proper, including an award of reasonable attorney's fees and costs of this action.

Dated: September 22, 2009.

Respectfully submitted,



A handwritten signature in black ink, appearing to read 'J. W. Gladstone', is written over a horizontal line. To the right of the signature is a large checkmark.

James W. Gladstone (D.C. Bar # 393283)
Womble Carlyle Sandridge & Rice, PLLC
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DEPARTMENT OF THE TREASURY
 ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
 WASHINGTON, D.C. 20220

September 24, 2007

4040000:KOJ
 5170
 20007R-391T

Hoo Tjhiang Han
 Director of Legal Compliance
 Kretek International, Inc.
 5449 Endeavour Court
 Moorpark, CA 93021

Dear Mr. Han:

This is in response to your request, dated July 11, 2007, to the Alcohol and Tobacco Tax and Trade Bureau (TTB) for a determination of the tax classification of "Djarum Special", a product imported by Kretek International.

You submitted with your request a product sample for analysis. The product sample that you submitted is listed below with the reference number designated by our Scientific Services Division (Laboratory).

Laboratory Sample Number	Sample Name and Description
T2007-00016-001	Djarum Special

The Internal Revenue Code of 1986 (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 41.11. In addition, the IRC and the TTB regulations distinguish between large cigars and small cigars for tax purposes: large cigars are cigars weighing more than 3 pounds per 1,000 units.

Our Laboratory conducted analyses of the filler, wrapper, and physical features of the product sample in question and provided the results to this division to



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Hoo Tjhiang Han

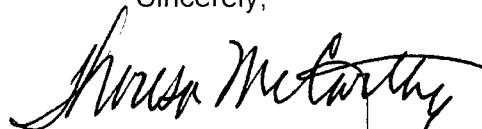
assist us in making a determination on the proper tax classification of this product under the above definitions. We base our determination on the laboratory analyses and on our evaluation of the packaging, labeling, and intended use of the product. We find that the product sample in question is consistent with the current analytical profile of a cigar, specifically a large cigar, and is properly classified as such for tax and regulatory purposes.


Please be advised that on October 25, 2006, TTB published in the Federal Register a notice of proposed rulemaking, Notice No. 65, Tax Classification of Cigars and Cigarettes, proposing changes to the regulations in 27 CFR Parts 40, 41, 44, and 45, that govern the classification and labeling of cigars and cigarettes for Federal excise tax purposes under the IRC. You may access copies of this notice and any comments we receive on this proposal online at www.ttb.gov/tobacco/tobacco_rulemaking.shtml.

Adoption of the proposed regulatory changes could affect the tax classification of the product you submitted, because once any changes to the regulations become effective, all tobacco products will be assessed under those standards for tax purposes. Accordingly, prior classifications of tobacco products such as this one will be subject to review under those standards.

If you have questions regarding this letter, please do not hesitate to contact Karl O. Joedicke by phone at 202-927-8210 or by e-mail at Karl.Joedicke@ttb.gov.

Sincerely,

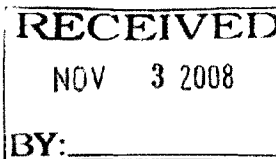


 Francis W. Foote
Director, Regulations and Rulings Division



DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

October 24, 2008



4040000: DBG
5200
2008R-392T

Mr. Hoo Tjhiang Han
Director of Tobacco Tax and Legal Compliance
Kretek International, Inc.
5449 Endeavour Court
Moorpark, CA 93021

Dear Mr. Han:

This is in response to your request, dated July 2, 2008, for advice from the Alcohol and Tobacco Tax and Trade Bureau (TTB) concerning the proper tax classification under the Internal Revenue Code of 1986 (IRC) of certain tobacco products Kretek intends to import. Along with your request, you submitted samples of tobacco products, described in your request as "cigars," each in a plain, white package (not a consumer package) bearing a single sticker, with some identifying information, on the front of the package. You also submitted, among other things: (1) graphic representations of packaging, which we understand to correspond to the sample products; (2) information concerning the composition of the tobacco filler of each product sample; and (3) statements from Schweitzer-Mauduit concerning the composition of the wrapper material. Each of the product samples is listed below along with the reference number assigned by TTB's Scientific Services Division (Laboratory), the information appearing on the sticker of each package, and the brand name and product information appearing on the graphic representation of packaging that we assume correspond to each sample.

Laboratory reference number	Sample name	Name and information appearing on corresponding packaging graphics
T-2008-00025-001	Black Cigar 693/BTS, 05/05/2008	Djarum Black 12 filtered clove cigars
T-2008-00025-002	D. Cigar Vanilla 2088, 16/11/2007	Djarum Vanilla 12 filtered clove cigars
T-2008-00025-003	D. Cigar Splash 2087, 16/11/2007	Djarum Splash 12 filtered clove cigars
T-2008-00025-004	D. Cigar Cherry 2089, 16/11/2007	Djarum Cherry 12 filtered clove cigars

The 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 section 5702(b)(2) defines the term "cigarette" as "any roll of

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Mr. Hoo Tjhiang Han

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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 41.11. In addition, the IRC and the TTB regulations distinguish between large cigars and small cigars for tax purposes: Small cigars are cigars weighing 3 pounds per 1,000 sticks or less, while large cigars are cigars weighing more than 3 pounds per 1,000 sticks.

The TTB Laboratory conducted analyses of the product samples submitted and provided the results to this division to assist us in making a determination of the proper tax classification of these products under the above definitions. Based on the Laboratory’s analyses and on our own evaluation, we find that each of the product samples you submitted is consistent with the analytical profile of a cigar.

According to the Laboratory report, with the exception of product sample T-2008-00025-001 (“Black Cigar 693/BTS, 05/05/2008”), each of the product samples in question weigh more than 3 pounds per 1,000 sticks and are, therefore, properly classified as large cigars for purposes of the IRC. Product sample T-2008-00025-001 (“Black Cigar 693/BTS, 05/05/2008”) weighs 3 pounds per 1,000 sticks and is, therefore, properly classified as a small cigar for purposes of the IRC.

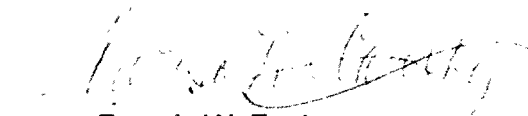
With regard to the packaging of the products, the TTB regulations at 27 CFR 41.73 require that every package of imported cigars, before removal subject to internal revenue tax, have adequately imprinted on it, or on a label securely affixed to it, the designation “cigars,” the quantity of cigars contained in the package, and, for small cigars, the classification of the product for tax purposes (that is, either “small” or “little”).

We have assumed that the packaging on which the information “Djarum Black 12 Filtered Clove Cigars” is imprinted corresponds to sample T-2008-00025-001 (“Black Cigar 693/BTS, 05/05/2008”), which we have determined to be a small cigar. As such, we find that the packaging intended for this product does not comply with the requirements of § 41.73 because it does not bear the proper classification of the product for tax purposes (that is, either “small” or “little”). The packaging intended for the remaining products each bears the designation “cigars” and the quantity of cigars contained in the package and, therefore, complies with the requirements of § 41.73.

Mr. Hoo Tjhiang Han

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If you have any questions regarding this letter, please contact Brady Groscost at (202) 927-0794 or Brady.Groscost@ttb.gov.



Francis W. Foote
Director, Regulations and Rulings Division



DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, D.C. 20220

June 12, 2009

4040000: DBG
5200

Mr. Hoo Tjhiang Han
Director of Tobacco Tax and Legal Compliance
Kretek International, Inc.
5449 Endeavour Court
Moorpark, CA 93021

Dear Mr. Han:

This is in response to your request, dated November 25, 2008, to the Alcohol and Tobacco Tax and Trade Bureau (TTB) Regulations and Rulings Division, for a ruling regarding the classification of a tobacco product you submitted, 'Djarum Black Cigar,' under the Internal Revenue Code of 1986 (IRC). In this request, you note that, in a letter from TTB dated October 24, 2008, TTB determined that a sample referred to as 'Djarum Black Cigar' was properly classified as a small cigar for Federal excise tax purposes. That sample was found to weigh 3.0 pounds per 1,000 sticks and you questioned that finding.

As you know, the 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 section 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 41.11. The IRC and the TTB regulations distinguish between large cigars and small cigars for tax purposes: Small cigars are cigars weighing 3 pounds per 1,000 sticks or less, while large cigars are cigars weighing more than 3 pounds per 1,000 sticks.

With regard to this second sample of the Djarum Black Cigar product, the TTB Scientific Services Division has found that it weighs 3.1 pounds per 1,000 sticks. Accordingly, the weight of this sample is consistent with that of a large cigar.

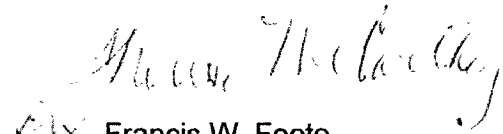
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Mr. Hoo Tjhiang Han

If you have any questions regarding this letter, please contact Brady Groscost by telephone at (202) 927-0794 or by email at Brady.Groscost@ttb.gov.


Francis W. Foote
Director, Regulations and Rulings Division