

UNITED STATES OF AMERICA
BEFORE THE DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of:)
)
Center for Tobacco Products,)
)
Complainant,)
)
v.)
)
Lee Lee and Lee Corporation)
d/b/a Crossroads Express,)
)
Respondent.)

**ADMINISTRATIVE COMPLAINT
FOR NO-TOBACCO-SALE ORDER**

FDA Docket No. FDA-2017-R-4807
CRD Docket No. T-17-5780

INTRODUCTION

1. The Center for Tobacco Products (“CTP”), Food and Drug Administration (“FDA”), United States Department of Health and Human Services, requests that the Administrative Law Judge (“ALJ”) impose a no-tobacco-sale order (“NTSO”) for a 30 consecutive day period on Lee Lee and Lee Corporation d/b/a Crossroads Express (“Respondent”) for repeatedly violating particular FDA tobacco regulations promulgated under Section 906(d) of the Federal Food, Drug, and Cosmetic Act (“Act”) (21 U.S.C. § 387f(d)), which are codified in 21 C.F.R. Part 1140. As shown in the following table¹ and described in more detail below, Respondent committed five repeated violations of particular FDA tobacco

¹ As explained in the Previous Case History section of this Complaint, CTP previously filed two civil money penalty (“CMP”) cases against Respondent. The table identifies Respondent’s original violations of FDA’s regulations in 21 C.F.R. Part 1140 and Respondent’s repeated violations of those particular regulations that occurred within a specified 36-month period after the original violations.

regulations within the 36-month period that included January 23, 2015 through March 28, 2017:

Charged Violation ^{2,3}	Violative Inspection Dates				Number of Repeated Violations
	03/08/2014	01/23/2015	08/21/2015	03/28/2017	
Selling cigarettes / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a) / 21 C.F.R. § 1140.14(a)(1)	OV	X	X	X	3
Failing to verify ID for cigarettes / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1) / 21 C.F.R. § 1140.14(a)(2)(i)	OV	X		X	2
FDA Action	Warning Letter Sent 05/08/2014	First CMP Initiated 06/03/2015 <i>FDA-2015-H-1796, C-15-2622</i>	Second CMP Initiated 12/09/2015 <i>FDA-2015-H-4457</i>	Current Inspection	Total: 5 Repeated Violations

LEGAL AUTHORITY

- The Act provides for an NTSO prohibiting the sale of tobacco products at a retail outlet against any person who commits repeated violations of requirements promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 21 U.S.C. § 333(f)(8). The regulations at 21 C.F.R. Part 1140 (hereafter, “Part 1140 regulations”) were issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)).

² “OV” indicates an original violation. “X” indicates a repeated violation of a particular requirement.

³ As of August 8, 2016, the effective date of FDA’s Final 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, available at <https://federalregister.gov/a/2016-10685>, the citations to certain FDA tobacco regulations have changed, although the text of those regulations has remained substantively the same. To account for the change in citation form, this chart and complaint will include references to the original and new citations indicated as Original (pre-August 8, 2016) Citation / New (post August 7, 2016) Citation. CTP counts as a “repeated violation” an action that violates the same textual regulation, regardless of whether the specific citation for such violation has changed.

75 Fed. Reg. 13,225 (Mar. 19, 2010). The term “repeated violations” in 21 U.S.C. § 333(f)(8) is defined as “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation.” See Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(A), 123 Stat. 1776, 1838 (2009).

3. CTP has provided public notice that retailers who have committed five or more repeated violations of particular Part 1140 regulations within a 36-month period may be subject to an NTSO for a period provided in the following table:

Number of NTSOs received by Retailer	Maximum Period of Time for NTSO
First NTSO	30 Consecutive Days
Second NTSO	6 Months
Third (and subsequent) NTSO	Permanent NTSO

See CTP, U.S. FDA., U.S. Dep’t of Health & Human Servs., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order (August 2015), *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

4. FDA has documented repeated violations of 21 C.F.R. Part 1140 at Respondent’s establishment, as detailed below.

CURRENT ALLEGATIONS

5. Respondent owns an establishment that does business under the name Crossroads Express and is located at 6300 East Highway 54, Athol, ID 83801.
6. An FDA-commissioned inspector conducted an inspection at Respondent’s establishment on March 28, 2017. During that inspection, Respondent committed the following violations:

- a. Selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on March 28, 2017, at approximately 9:45 AM; and
 - b. Failing to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on March 28, 2017, at approximately 9:45 AM.
7. On March 31, 2017, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on March 28, 2017, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 9:45 AM. This Notice stated that other potential violations of federal tobacco law may have been observed, and further stated that if, after review, CTP determined that there was a violation of federal law, the establishment may receive further notification from FDA.

PREVIOUS CASE HISTORY

8. Respondent has been the subject of two prior CMP actions based on its violations of the Part 1140 regulations.
9. CTP initiated its first CMP action against Respondent on June 3, 2015, alleging that Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)), and failed to verify the age of a person purchasing

cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on March 8, 2014 and January 23, 2015. See Compl., FDA Docket Number FDA-2015-H-1796, CRD Docket Number C-15-2622. ("First CMP Action"). The First CMP Action was closed after Kay Lee, d/b/a Cross Roads Express admitted all of the allegations in the Complaint and paid the agreed upon penalty.⁴ In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See First CMP Action, Attachment to Notice of Settlement Agreement.

10. On December 9, 2015, CTP initiated its second CMP action against Respondent, alleging that, in addition to the violations alleged in the First CMP Action, Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) on August 21, 2015. See Compl., FDA Docket Number FDA-2015-H-4457. "Second CMP Action," attached at Exhibit 1. The Second CMP Action was concluded with an Initial Decision and Default Judgment dated August 15, 2016, finding Respondent liable for the March 8, 2014, January 23, 2015, and August 21, 2015 violations. See Initial Decision and Default Judgment, Second CMP Action, attached at Exhibit 2.

EVIDENCE SUPPORTING CURRENT REQUEST FOR NTSO

11. With its most recent sale to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) and failure to verify identification (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on

⁴ Lee Lee and Lee Corporation has owned this establishment during all FDA inspections. Kyoung Lee, who signed the Acknowledgement Form for the previous CMP and identified himself as the establishment's owner, is the Secretary of Lee Lee and Lee Corporation. The address of the Registered Agent of Lee Lee and Lee Corporation is the same as that of the establishment.

March 28, 2017, see paragraph 6 of this Complaint, Respondent committed the following five repeated violations of regulations that it originally violated on March 8, 2014, in the 36-month period that included January 23, 2015 to March 28, 2017:

- a. Three repeated violations of selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1), on January 23, 2015, August 21, 2015, and March 28, 2017; and
- b. Two repeated violations of failing to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i), on January 23, 2015 and March 28, 2017.

Accordingly, Respondent has committed a total of five repeated violations of particular requirements in 21 C.F.R. Part 1140 within a 36-month period and is subject to an NTSO. See 21 U.S.C. § 333(f)(8).

OPTIONS FOR RESPONDING TO COMPLAINT

12. Respondent must respond to this Complaint. The cover letter provides information on options for responding. Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. 21 C.F.R. § 17.9. The Answer will be deemed to be a request for a hearing, unless the Answer states otherwise. Failure to file an Answer within 30 days after service of the Complaint may result in a default order. 21 C.F.R. § 17.11. The Answer must be filed with the Departmental Appeals Board, Civil Remedies Division, 330 Independence Ave., S.W., Cohen Building, Room G-644 (MS

6132), ATTN: FDA NTSO, Washington, D.C. 20201. The Answer must include both the FDA Docket Number and CRD Docket Number, which are found at the top of this document.

13. Respondent has the right, but is not required, to retain counsel for representation.

REQUEST FOR RELIEF

14. CTP respectfully requests that the ALJ impose a no-tobacco-sale order preventing Respondent from selling cigarettes, cigarette tobacco, roll-your own tobacco, smokeless tobacco, and covered tobacco products for a 30 consecutive day period.

DATED: August 7, 2017

Respectfully submitted,

/s/

Ann M. Oxenham

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