

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.)
)
8 Merchants, LLC)
d/b/a 7-Eleven 35532A,)
)
Respondent.)

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

FDA Docket No. FDA-2017-R-0593
CRD Docket No. T-17-2032

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 calendar day period on 8 Merchants, LLC, d/b/a 7-Eleven 35532A (“Respondent”) for repeatedly violating FDA’s 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

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.

committed five repeated violations of FDA's tobacco regulations within the 36-month period that included February 27, 2015 to March 19, 2016.

Charged Violation ^{2,3}	Violative Inspection Dates				Number of Repeated Violations
	11/12/2014	02/27/2015	08/17/2015	03/19/2016	
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
<u>FDA Action</u>	Warning Letter Sent 12/11/2014	First CMP Initiated 06/30/2015 <i>FDA-2015-H-2166, C-15-2953</i>	Second CMP Initiated 12/04/2015 <i>FDA-2015-H-4362</i>	Current Complaint	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.

² "OV" indicates an original violation. "X" indicates a repeated violation.

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. The chart includes references to the original and new citations; 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.

§ 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)). 75 Fed. Reg. 13,225 (Mar. 19, 2010). “Repeated violations” is defined as at least five violations of particular requirements over a 36-month period at a particular retail outlet. 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 Calendar 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 multiple 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 7-Eleven 35532A and is located at 819 Virginia Street, Suite C1, Seattle, WA 98101.
6. An FDA-commissioned inspector conducted an inspection at Respondent’s establishment on March 19, 2016. 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). Specifically, a person younger than 18 years of age was able to purchase a package of Camel cigarettes on March 19, 2016, at approximately 4:18 PM;
 - 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). Specifically, the minor's identification was not verified before the sale, as detailed above, on March 19, 2016, at approximately 4:18 PM.
7. On March 25, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on March 19, 2016, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 4:18 PM. 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 30, 2015, alleging that Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R.

§ 1140.14(a)) and failed to verify the age of a person purchasing covered tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1)) on November 12, 2014 and February 27, 2015. See Compl., FDA Docket Number FDA-2015-H-2166, CRD Docket Number C-15-2953 ("First CMP Action"). The First CMP Action was closed after 8 Merchants, LLC, d/b/a 7-Eleven 35532A admitted all of the allegations in the Complaint and paid the agreed upon penalty. 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 4, 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)) on August 17, 2015. See Compl., FDA Docket Number FDA-2015-H-4362. ("Second CMP Action"), attached at Exhibit 1. The Second CMP Action was closed after 8 Merchants, LLC d/b/a 7-Eleven 35532A admitted all of the allegations in the Complaint and paid the agreed upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See Second CMP Action, Attachment to Notice of Settlement Agreement, 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)) and failure to verify identification (21 C.F.R. § 1140.14(b)(1)) on March 19, 2016, see paragraph 6 of this complaint, Respondent committed the following five repeated violations of regulations that it originally violated on November 12, 2014, in the 36-month period that included February 27, 2015 to March 19, 2016:
 - a. Three repeated violations of selling covered tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1), on February 27, 2015, August 17, 2015, and March 19, 2016; and
 - b. Two repeated violations of failing to verify the age of a person purchasing covered tobacco products 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 February 27, 2015 and March 19, 2016.

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 calendar day period.

DATED: February 01, 2017

Respectfully submitted,

/s/

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