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,	)	
	)	**ADMINISTRATIVE COMPLAINT**
v.	)	**FOR NO-TOBACCO-SALE ORDER**
	)	
Manson, LLC	)	FDA Docket No. FDA-2016-R-3926
d/b/a Sunoco,	)	CRD Docket No. T-17-822
	)	
Respondent.	)	
	)	

INTRODUCTION

1. The Center for Tobacco Products ("CTP"), Food and Drug Administration ("FDA"), United States Department of Health and Human Services, seeks to have the Secretary impose a no-tobacco-sale order ("NTSO") for a period of 30 consecutive calendar days on Manson, LLC d/b/a Sunoco (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)). As described in more detail below, FDA-commissioned inspectors observed five repeated violations of FDA's tobacco regulations over a 36-month period, as shown in the following table:[1]

[1] The table identifies only Respondent's violations of regulations promulgated under Section 906(d) of the Act, 21 U.S.C. § 387f(d), and excludes any repeated violations that occurred outside of the 36-month period and any violations of other Act sections that are not at issue in this case.

	Violative Inspection Dates				
Charged Violation[2, 3]	11/04/2013	04/03/2014	02/12/2015	01/28/2016	**Number of Repeated Violations**
Selling cigarettes / cigarette tobacco / 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 / cigarette tobacco / 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 01/06/2014	First CMP Initiated 10/14/2014 *FDA-2014-H-1542; C-15-48*	Second CMP Initiated 07/27/2015 *FDA-2015-H-2441; C-15-3275*	Current Complaint	**Total: 5 Repeated Violations**

LEGAL AUTHORITY

2. FDA has the authority to impose an NTSO prohibiting the sale of tobacco products at a retail outlet on 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). "Repeated violations" is defined as at least five violations of particular requirements over a 36-month period at a particular retail outlet.

[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 (hereafter, "Deeming Regulation"), the citations to certain FDA tobacco regulations have changed, although the text of those regulations has remained 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.

See Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(A), 123 Stat. 1776, 1838 (2009).

3. The Act prohibits the misbranding of a tobacco product while such product is held for sale after shipment of the product or its components in interstate commerce. 21 U.S.C. § 331(k).

4. A tobacco product is deemed to be misbranded if it is sold or distributed in violation of regulations issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b).

5. The regulations at 21 C.F.R. Part 1140 were issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)). Therefore, selling or distributing a tobacco product in violation of these regulations causes that tobacco product to be misbranded.

6. Retailers who have committed five or more repeated violations of particular requirements promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)) within a 36-month period are 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.

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

CURRENT ALLEGATIONS

8. Respondent owns an establishment that does business under the name Sunoco and is located at 2350 East North Street, Greenville, SC 29607.

9. Respondent's establishment receives tobacco products in interstate commerce, including Newport Box cigarettes and Newport Kings cigarettes, and holds them for sale after shipment in interstate commerce.

10. On January 28, 2016, an FDA-commissioned inspector conducted an inspection of Sunoco. During that inspection, Respondent committed the following violations:

    a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on January 28, 2016, at approximately 3:40 PM; and

    b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on January 28, 2016, at approximately 3:40 PM.

11. On February 1, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on January 28, 2016, and that during this inspection a minor was able to enter the

establishment and purchase a regulated tobacco product at approximately 3:40 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

12. Respondent has been the subject of two prior CTP Civil Money Penalty ("CMP") actions based on its violations of the Act. During the two prior CMP actions, CTP listed Apu Karam and Atu Karamchandani as Respondent, respectively. Documents from the current inspection, originally issued in 2004, show that Manson, LLC is the corporate owner of the establishment. As such, the Respondent in the current complaint is Manson, LLC.

13. On July 27, 2015, CTP initiated its most recent CMP action against Respondent, alleging that FDA-commissioned inspectors documented the following violations at Respondent's establishment:

    a. Sale to a minor (21 C.F.R. § 1140.14(a)) on February 12, 2015, April 3, 2014, and November 4, 2013; and

    b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1)) on February 12, 2015 and November 4, 2013.

See Compl., FDA Docket Number FDA-2015-H-2441, CRD Docket Number C-15-3275. The CMP Action concluded with a final default judgment against Atu Karamchandani d/b/a Sunoco, finding that all of the violations alleged in the

Complaint occurred. *See* Initial Decision and Default Judgment FDA Docket Number FDA-2015-H-2441, CRD Docket Number C-15-3275 (CRD Decision CR4240).

14. On October 14, 2014, CTP initiated its first CMP action against Respondent, alleging that FDA-commissioned inspectors documented the following violations at Respondent's establishment:

    a. Sale to a minor (21 C.F.R. § 1140.14(a)) on April 3, 2014 and November 4, 2013; and

    b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1)) on November 4, 2013.

    See Compl., FDA Docket Number FDA-2014-H-1542, CRD Docket Number C-15-48. The CMP Action was closed after Apu Karam d/b/a Sunoco 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* Attachment to Notice of Settlement Agreement FDA Docket Number FDA-2014-H-1542, CRD Docket Number C-15-48.

15. As described in the paragraphs above, Respondent has committed:

    a. Three repeated violations and one original violation of sale to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1); and

    b. Two repeated violations and one original violation of failure to verify the age of a person purchasing 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).

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.

OPTIONS FOR RESPONDING TO COMPLAINT

16. 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.

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

REQUEST FOR RELIEF

18. CTP respectfully requests that this Court impose a no-tobacco-sale order for cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products be imposed on Respondent for a period of 30 consecutive calendar days.

DATED: November 17, 2016

Respectfully submitted,

/s/

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