

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.)
)
Yemco Fuel, Inc.)
d/b/a Marathon,)
)
Respondent.)

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

FDA Docket No. FDA-2016-R-3857
CRD Docket No. T-17-781

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 consecutive six month period against Yemco Fuel, Inc., d/b/a Marathon (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 committed five repeated violations of FDA’s tobacco regulations within the 36-month period that

¹ As explained in the Previous Case History section of this Complaint, this is the second NTSO case filed against Respondent and CTP also 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. The table does not include Respondent’s repeated violations that fall outside of the specified 36-month period.

included March 29, 2014 to August 26, 2016 (hereafter “specified 36-month period”):

Charged Violation ^{2, 3}	Violative Inspection Dates				Number of Repeated Violations
	01/25/2013	03/29/2014	03/21/2015	8/26/2016	
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
<u>FDA Action</u>	Warning Letter Sent 02/07/2013	Second CMP Initiated 10/08/2014 <i>FDA-2014-H-1513; C-15-20</i>	First NTSO Initiated 10/26/2015 <i>FDA-2015-R-3479</i>	Current Complaint	Total: 5 Repeated Violations

LEGAL AUTHORITY

2. 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.

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.

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 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>.

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 Marathon and is located at 4111 East 7 Mile Road, Detroit, MI 48234.
6. On August 26, 2016, an FDA-commissioned inspector conducted an inspection at Respondent’s establishment. During that inspection, FDA inspectors documented that Respondent committed the following violations:

- a. Selling cigarettes or smokeless tobacco 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 100s cigarettes on August 26, 2016, at approximately 12:51 PM; 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(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on August 26, 2016, at approximately 12:51 PM.
7. On August 31, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on August 26, 2016, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 12:51 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 and one prior NTSO action based on its violations of the Part 1140 regulations.
9. CTP initiated its first CMP action against Respondent on October 29, 2013, alleging that Respondent sold Newport Box 100s cigarettes to a minor (21 C.F.R. § 1140.14(a)) and failed 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 January 25 and May 25, 2013. See Compl., FDA Docket No. FDA-2013-H-1264; CRD Docket No. C-14-53 ("First CMP Action"), ¶¶ 1, 10. The First CMP action concluded with an Initial Decision and Default Judgment dated December 23, 2013, finding Respondent liable for the January 25 and May 25, 2013 violations. See Initial Decision and Default Judgment, First CMP Action.⁴

10. On October 8, 2014, CTP initiated its second CMP action against Respondent, alleging that, in addition to the violations alleged in the First CMP Action, Respondent sold tobacco products to a minor (21 C.F.R. § 1140.14(a)) on March 29, 2014. See Compl., FDA Docket Number FDA-2014-H-1513, CRD Docket Number C-15-20 ("Second CMP Action"). The Second CMP Action was closed after Yemco Fuel, Inc. / Nakeeb Hassan d/b/a Marathon admitted all of the allegations in the Complaint and paid the agreed upon penalty. In acknowledging that the violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See Second CMP Action, Attachment to Notice of Settlement Agreement.
11. On October 26, 2015, CTP initiated the first NTSO action against Respondent, alleging that Respondent originally sold tobacco products to a minor (21 C.F.R. § 1140.14(a)) and failed 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 January 25, 2013, and committed the

⁴ CTP is not counting the May 25, 2013 violations as "repeated violations" in this Second NTSO Complaint because they fall outside the specified 36-month period.

following five repeated violations of such regulations in the 36-month period that included May 25, 2013 to March 21, 2015:

- a. Three repeated violations of sale to a minor (21 C.F.R. § 1140.14(a)) on May 25, 2013, March 29, 2014, and March 21, 2015; and
- b. Two repeated violations of failing 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 May 25, 2013 and March 21, 2015.

See Compl., FDA Docket Number FDA-2015-R-3479 ("First NTSO Action"). The First NTSO Action concluded after Yemco Fuel, Inc. d/b/a Marathon admitted all of the allegations in the Complaint and agreed to an NTSO, and the ALJ issued the NTSO for the agreed-upon time period. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See First NTSO Action, Attachment to Notice of Settlement Agreement.

EVIDENCE SUPPORTING CURRENT REQUEST FOR NTSO

12. With its most recent sale to a minor (21 C.F.R. § 1140.14(a)(1)) and failure to verify identification (21 C.F.R. § 1140.14(a)(2)(i)) on August 26, 2016, see paragraph 6 of this Complaint, Respondent committed the following five repeated violations of regulations that it originally violated on January 25, 2013, in the 36-month period that included March 29, 2014 and August 26, 2016:

- a. Three repeated violations of selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1), on March 29, 2014, March 21, 2015, and August 26, 2016; and
- b. Two repeated violations of failing 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), on March 21, 2015, and August 26, 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

13. 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.

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

REQUEST FOR RELIEF

15. 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 consecutive six month period.

DATED: November 15, 2016

Respectfully submitted,

/s/

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