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. US Liberty Inc. d/b/a Loch Raven Gulf, Respondent.	**ADMINISTRATIVE COMPLAINT FOR NO-TOBACCO-SALE ORDER** CRD Docket No. T-17-5661 FDA Docket No. FDA-2017-R-4669

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 US Liberty Inc., d/b/a Loch Raven Gulf ("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 table[1] and described in more detail below, Respondent committed seven repeated violations of particular FDA tobacco regulations within the 36-month period that included July 9, 2014

[1] As explained in the Previous Case History section of this Complaint, CTP previously filed three 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.

to January 19, 2017:

	Violative Inspection Dates					
Charged Violation[2,3]	02/26/2014	07/09/2014	04/22/2015	01/12/2016	01/19/2017	**Number of Repeated Violations**
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**	**X**	**4**
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**		**X**	**3**
FDA Action	Warning Letter Sent 05/01/2014	First CMP Initiated 12/17/2014 FDA-2014-H-2208 C-15-686	Second CMP Initiated 07/20/2015 FDA-2015-H-2350 C-15-3183	Third CMP Initiated 09/06/2016 FDA-2015-H-2571 T-16-1821	Current Inspection	**Total: 7 Repeated Violations**

[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.

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)). 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 Loch Raven Gulf and is located at 8623 Loch Raven Boulevard, Baltimore, MD 21286.

6. An FDA-commissioned inspector conducted an inspection at Respondent's establishment on January 19, 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 Newport Box 100s cigarettes on January 19, 2017, at approximately 1:44 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(b)(1) / 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on January 19, 2017, at approximately 1:44 PM.

7. On January 25, 2017, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on January 19, 2017, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 1:44 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 three prior CMP actions based on its violations of the Part 1140 regulations.

9. On December 17, 2014, CTP initiated its first CMP action against Respondent, 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 February 26, 2014 and July 9, 2014. *See* Compl., FDA Docket Number FDA-2014-H-2208, CRD Docket Number C-15-686. ("First CMP Action"). The First CMP Action concluded with an Initial Decision and Default Judgment entered on February 12, 2015, finding Respondent liable for the February 26, 2014 and July 9, 2014 violations. *See* Initial Decision and Default Judgment, First CMP Action.

10. On July 20, 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)) 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 April 22, 2014. *See* Compl., FDA Docket Number FDA-2015-H-2350, CRD Docket Number C-15-3183. ("Second CMP Action"). The Second CMP Action concluded with an Initial Decision and Default Judgment entered on September 16, 2015, finding Respondent liable for the April 22, 2015 violations. *See* Initial Decision and Default Judgment, Second CMP Action.

11. On September 6, 2016, CTP initiated its third CMP action against Respondent, alleging that, in addition to the violations alleged in the First and Second CMP Actions, Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) on January 12, 2016. *See* Compl., FDA Docket Number FDA-2016-H-2571, CRD Docket Number T-16-1821. ("Third CMP Action"). The Third CMP Action concluded with an Initial Decision and Default Judgment entered on November 3, 2016, finding Respondent liable for the January 12, 2016 violations. *See* Initial Decision and Default Judgment, Third CMP Action.

EVIDENCE SUPPORTING CURRENT REQUEST FOR NTSO

12. 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 January 19, 2017, *see* paragraph 6 of this Complaint, Respondent committed the following seven repeated violations of regulations that it originally violated on February 26, 2014, in the 36-month period that included July 9, 2014 to January 19, 2017:

    a. Four 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 July 9, 2014, April 22, 2015, January 12, 2016, and January 19, 2017; and

    b. Three 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 July 9, 2014, April 22, 2015, and January 19, 2017.

Accordingly, Respondent has committed a total of seven 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 30 consecutive day period.

DATED: July 31, 2017

Respectfully submitted,

/s/

Joshua Davenport
Attorney for Complainant
Center for Tobacco Products
United States Food and Drug Administration
White Oak 31, Room 4586
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (301) 796-6717
Fax: (301) 847-8638
Email: joshua.davenport@fda.hhs.gov