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** |
| | ) | |
| Guru Express Corporation | ) | FDA Docket No. FDA-2016-R-2765 |
| d/b/a Gulf Express, | ) | CRD Docket No. T-16-1958 |
| | ) | |
| 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 calendar days on Guru Express Corporation, d/b/a Gulf Express (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 seven 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] | 07/04/2013 | 11/19/2013 | 09/03/2014 & 09/04/2014 | 12/06/2015 | **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** | **X** | **3** |
| Having a self-service display in a facility not restricted to 18+, 21 C.F.R. § 1140.16(c) | **OV** | | **X** | | **1** |
| **FDA Action** | Warning Letter Sent 08/22/2013 | First CMP Initiated 07/07/2014 *FDA-2014-H-0921 C-14-1412* | Second CMP Initiated 03/18/2015 *FDA-2015-H-0810 C-15-1643* | Current Complaint | **Total: 7 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

[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.

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. *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 Gulf Express and is located at 46 US Highway 9, Manalapan, NJ 07726.

9. Respondent's establishment receives tobacco products in interstate commerce, including Marlboro Gold Pack cigarettes, Red Man smokeless tobacco, Top cigarette tobacco, and American Spirit cigarette tobacco, among others, and holds them for sale after shipment in interstate commerce.

10. On December 6, 2015, an FDA-commissioned inspector conducted an inspection of Gulf Express. 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 Marlboro Gold Pack cigarettes on December 6, 2015, at approximately 12:08 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 December 6, 2015, at approximately 12:08 PM.

11. On December 9, 2015, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on December 6, 2015, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 12:08 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.

13. On March 18, 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 September 3, 2014, November 19, 2013, and July 4, 2013;

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 September 3, 2014, November 19, 2013, and July 4, 2013; and

c. Use of a self-service display in a non-exempt facility (21 C.F.R. § 1140.16(c)) on September 4, 2014 and July 4, 2013.

*See* Compl., FDA Docket Number FDA-2015-H-0810, CRD Docket Number C-15-1643. The CMP Action was closed after Guru Express Corporation, d/b/a Gulf Express 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-2015-H-0810, CRD Docket Number C-15-1643.

14. On July 7, 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 November 19, 2013 and July 4, 2013;

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 19, 2013 and July 4, 2013; and

c. Use of a self-service display in a non-exempt facility (21 C.F.R. § 1140.16(c)) on July 4, 2013.

*See* Compl., FDA Docket Number FDA-2014-H-0921, CRD Docket Number C-14-1412. The CMP Action was closed after Guru Express Corporation, d/b/a Gulf Express 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-2014-H-0921, CRD Docket Number C-14-1412.

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);

    b. Three 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); and

    c. One repeated violation and one original violation of use of a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c)).

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.

## 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 a period of 30 calendar days on Respondent.

DATED: September 16, 2016

Respectfully submitted,

/s/

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